Mark R. Elam, Chairman
Charles M. Joye, II, P.E., Secretary
J.B. (Sonny) Kinney
Seema Shrivastava-Patel

Board:
Richard V. Lee, Jr.
Alex A. Singleton
Jim P. Creel, Jr.

South Carolina Board of Health and Environmental Control

Agenda

September 12, 2019

Call to Order – 10:00 a.m., Board Room (#3420)
South Carolina Department of Health and Environmental Control,
2600 Bull Street, Columbia, S.C.

1. Minutes of August 08, 2019 meeting

2. Administrative and Consent Orders issued by Health Regulation

3. Administrative and Consent Orders issued by Environmental Affairs

4. Notice of Proposed Regulation Amending R.30-1, *Statement of Policy*, and R.30-14, *Administrative Procedures*, South Carolina Coastal Zone Management Act

5. Notice of Proposed Regulation Amending R.61-32, *Soft Drink and Water Bottling Plants*, and Repealing R.61-54, *Wholesale Commercial Ice Manufacturing*

6. Notice of Proposed Regulation Amending R.61-36, *Frozen Desserts*, and Repealing R.61-35, *Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products*

7. Notice of Proposed Regulation Repealing R.61-1, *Medical and Dental Scholarship Fund*

8. Agency Affairs

Executive Session (if needed)

Adjournment

Note: The next scheduled meeting is October 10, 2019.

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

September 12, 2019

( ) ACTION/DECISION
(X) INFORMATION

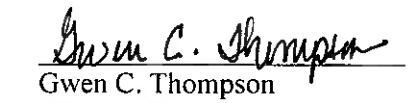
I. **TITLE:** Health Regulation Administrative and Consent Orders.

II. **SUBJECT:** Health Regulation Administrative Orders and Consent Orders for the period of July 1, 2019 through July 31, 2019.

III. **FACTS:** For the period of July 1, 2019 through July 31, 2019, Health Regulation reports 2 Administrative Orders and 5 Consent Orders totaling $61,600 in assessed monetary penalties.

Health Regulation Bureau	Facility, Service, Provider, or Equipment Type	Administrative Orders	Consent Orders	Emergency Suspension Orders	Assessed Penalties
Health Facilities Licensing	Hospital	1	0	0	$10,000
	Nursing Home	0	1	0	$7,850
	Community Residential Care Facility	0	2	0	$24,200
Radiological Health	Chiropractic	0	2	0	$4,550
	Radioactive Material	1	0	0	$15,000
TOTAL		**2**	**5**	**0**	**$61,600**

Submitted By:



Gwen C. Thompson
Interim Director
Health Regulation

HEALTH REGULATION ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

September 12, 2019

Bureau of Health Facilities Licensing

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Hospital	104	15,130

1. G. Werber Bryan Psychiatric Hospital – Columbia, SC

Inspections and Investigations: The Department conducted a complaint investigation in February 2019 that resulted in regulatory violations.

Violations: The Department cited the facility for failing to ensure nursing services were organized and staffed to provide safe and appropriate care to patients. Specifically, facility staff's restraint of a patient was unsafe and inappropriate care that was in violation of the facility's nursing policy on personal holds. The Department also cited the facility for failing to provide training to all staff to ensure and maintain their understanding of their duties and responsibilities. Specifically, the Department found that facility staff did not have training as required by the facility's Behavior Emergency Stabilization Training (BEST) policy.

Enforcement Action: The parties conducted an enforcement conference and the parties were unable to reach an agreement to resolve the enforcement. As a result, the Department issued an administrative order imposing a $10,000 civil monetary penalty against the facility. The facility has made the required payment.

Prior Actions: None.

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Nursing Home	194	20,462

2. Heritage Home of Florence – Florence, SC

Inspections and Investigations: The Department conducted a complaint investigation in August 2018 along with a follow-up inspection in January 2019, and found several violations on both visits.

Violations: The Department cited the facility for 16 violations during the August 2018 and January 2019 inspections, that all involved medication administration and management requirements.

Enforcement Action: The parties conducted an enforcement conference, during which the facility provided information regarding the comprehensive investigation and ongoing corrective measures they were undertaking in response to the citations. The parties agreed to resolve the matter with a consent order, whereby the facility agreed to pay $4,850 of an assessed monetary penalty of $7,850. The facility has made

the required payment. The facility agreed to ensure all corrective action has been undertaken and to attend a compliance assistance meeting with the Department.

Prior Actions: None.

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Community Residential Care Facility	501	21,429

3. Twilite Manor Adult Residential Care – Cayce, SC

Inspections and Investigations: The Department conducted three respective complaint investigations in December 2017, July 2018, and October 2018, as well as having conducted routine inspections in January 2018 and August 2018, and found numerous violations and repeat violations throughout the visits.

Violations: The Department cited the facility for an accumulated total of 48 violations throughout all 2017 and 2018 inspections and investigations. The Department found the following violations, including, but not limited to: Staff training, employment of an administrator, staff and resident assessments, incident reporting, resident records and individual care plans, resident monies, tuberculosis screening, medication administration, and security of oxygen cylinders.

Enforcement Action: The parties conducted an enforcement conference and agreed to resolve the matter with a consent order imposing a $19,600 monetary penalty. The facility agreed to pay $9,600 in four installments of $2,450. The facility has made the first required payment. The facility has also agreed to attend a compliance assistance meeting with the Department.

Prior Actions: None.

4. Pondview Residential Care Home #1 – Blythewood, SC

Inspections and Investigations: The Department conducted a routine inspection in September 2018 and a complaint investigation in February 2019, and found many violations in both visits.

Violations: The Department cited the facility a combined total of 30 violations during the 2018 and 2019 inspections and investigations. The Department found the following violations, including, but not limited to: Access to the facility during investigation, policies and procedures, staff records, staffing numbers, staff training, incident reporting, resident records, and medication administration.

Enforcement Action: The parties conducted an enforcement conference and agreed to resolve the matter with a consent order imposing a $4,600 monetary penalty. The facility agreed to pay $2,600 in four installments of $650. The facility has made the first required payment. The facility has also agreed to attend a compliance assistance meeting with the Department.

Prior Actions: None.

Bureau of Radiological Health

Facility Type	Total # of Registered Facilities
Chiropractic	482

5. Dove Chiropractic – Piedmont, SC

Inspections and Investigations: The Department conducted several routine inspections, including August 2010, April 2014, and November 2017, and found that the registrant repeatedly violated the same regulatory requirement.

Violations: The Department found that the registrant violated the X-Rays Regulation by failing to show records of equipment performance testing during the most recent inspection, and had been cited for the same violation on two previous inspections. Specifically, the registrant failed to show that their medical x-ray equipment had been tested annually. The registrant also failed to have a radiation area survey performed within 30 days after installation of x-ray equipment as required by the regulation. Furthermore, the registrant failed to correct violations within 60 days from the date of citation.

Enforcement Action: The parties conducted an enforcement conference and agreed to resolve the matter with a consent order. In July 2019, the parties executed a consent order imposing a civil monetary penalty of $2,550 against the registrant. The registrant was required to pay $637.50 within 30 days of executing the consent order, with the remaining $1,912.50 held in abeyance for 24 months. The facility has made the first required payment.

Prior Actions: None.

6. Precision Chiropractic Spartanburg – Spartanburg, SC

Inspections and Investigations: The Department conducted a routine inspection on October 17, 2017 and found multiple regulatory violations.

Violations: The Department found that the registrant violated the X-Rays Regulation by failing to display signs bearing the universal radiation symbol with the words "CAUTION, RADUATION AREA" on it, along with failing to display a sign notifying patients to inform physicians of a possibly pregnancy. The Department also found that the facility failed to have the x-ray control permanently mounted in an area that requires the operator to remain in a protected area during the entire x-ray exposure. Other violations include the registrant failing to produce records of lead apron testing, failing to produce records of annual equipment performance, failing to produce records illustrating performance of a repeat analysis program, and failing to show records documenting tests required by protocol, as established by the manufacturer's operating manual of the digital imaging acquisition system.

Enforcement Action: The parties conducted an enforcement conference and agreed to resolve the matter with a consent order imposing a $2,000 civil monetary penalty. The facility agreed to pay $200 within 30 days of executing the consent order, with the remaining $1,800 stayed. The facility has made the first required payment.

Prior Actions: None.

License Type	Total # of Radioactive Material Licensees
Radioactive Material	332

7. GS2 Engineering and Environmental Consultants – North Charleston, SC

Inspections and Investigations: The Department conducted routine inspections on December 17, 2013 and February 14, 2019, and found several violations, including repeat violations.

Violations: The Department found that the licensee failed to perform tests for leakage and contamination on sealed sources at intervals not to exceed 12 months, as well as failed to conduct a physical inventory every six months to account for all sources and devices received and possessed under the license. The licensee also failed to maintain records of doses receives by all individuals whom monitoring is required. These three infractions are all repeat violations, as the Department cited the same failures during the previous routine inspection conducted in 2013. Moreover, the licensee has failed to provide training records to the Department, failed to have a utilization log for gauging devices containing radioactive materials, and failed to keep transfer records of all sources of radiation.

Enforcement Action: The parties conducted an enforcement conference and agreed to resolve the matter if the facility provided the radiation safety records to the Department. The facility has failed to provide such records after multiple attempts of collecting the necessary information. As a result, the Department issued an administrative order imposing a $15,000 civil monetary penalty against the facility.

Prior Actions: A Consent Order was executed between the parties in 2007. The Department imposed a monetary penalty in the amount of $1,000.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
September 12, 2019

_____ ACTION/DECISION

___X___ INFORMATION

1. **TITLE:** Administrative and Consent Orders issued by the Office of Environmental Affairs.

2. **SUBJECT:** Administrative and Consent Orders issued by the Office of Environmental Affairs during the period July 1, 2019 through July 31, 2019.

3. **FACTS:** For the reporting period of July 1, 2019 through July 31, 2019, the Office of Environmental Affairs issued one hundred twenty (120) Consent Orders with total assessed civil penalties in the amount of one hundred twenty-seven thousand, three hundred dollars $127,300.00 and Consent Agreements. Also, four (4) Administrative Orders were reported during this period with total assessed civil penalties in the amount of four thousand, five hundred dollars $4,500.00.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Agreements	Consent Orders	Assessed Penalties
Land and Waste Management					
UST Program	0	0	0	3	$4,000.00
Aboveground Tanks	0	0	0	0	0
Solid Waste	0	0	0	1	$500.00
Hazardous Waste	0	0	0	0	0
Infectious Waste	0	0	0	0	0
Mining	0	0	0	1	$1,000.00
SUBTOTAL	**0**	**0**	**0**	**5**	**$5,500.00**
Water					
Recreational Water	0	0	0	22	$17,000.00
Drinking Water	0	0	0	4	$9,000.00
Water Pollution	0	0	0	4	$11,200.00
Dam Safety	0	0	0	0	0
SUBTOTAL	**0**	**0**	**0**	**30**	**$37,200.00**
Air Quality					
SUBTOTAL	**0**	**0**	**0**	**0**	**0**
Environmental Health Services					
Food Safety	2	$4,500.00	0	75	$82,600.00
Onsite Wastewater	2	0	0	10	$2,000.00
SUBTOTAL	**4**	**$4,500.00**	**0**	**85**	**$84,600.00**
OCRM					
SUBTOTAL	**0**	**0**	**0**	**0**	**0**
TOTAL	**4**	**$4,500.00**	**0**	**120**	**$127,300.00**

Submitted by:

Myra C. Reece

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
September 12, 2019

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Consent Order 19-0107-UST
Order Date: July 3, 2019
Individual/Entity: **Vahin, LLC**
Facility: 903 Market and Grill
Location: 1926 McBee Highway
Jefferson, SC 29718-9471
Mailing Address: Same
County: Kershaw
Previous Orders: None
Permit/ID Number: 05361
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-60(A) seq. (2018).

Summary: Vahin, LLC (Individual/Entity), owns underground storage tanks located in Jefferson, South Carolina. On April 3, 2019, the Department issued a Notice of Alleged Violation because underground storage tank registration fees had not been paid for fiscal years 2013 through 2018. The Individual/Entity has violated the SUPERB Act as follows: failed to pay to the Department annual underground storage tank registration fees.

Action: The Individual/Entity is required to: pay underground storage tank registration fees for fiscal years 2013 through 2018 in the amount of eight thousand, three hundred forty-nine dollars ($8,349.00) and pay a **suspended penalty** in the amount of three thousand, six hundred dollars **($3,600.00)** should any requirement of the Order not be met.

2) Order Type and Number: Consent Order 19-0117-UST
Order Date: July 22, 2019
Individual/Entity: **General Services Administration**
Facility: Strom Thurmond Federal Building
Location: 1835 Assembly Street
Columbia, SC 29201
Mailing Address: 1835 Assembly Street, Suite 758
Columbia, SC 29201
County: Richland
Previous Orders: None
Permit/ID Number: 19946
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-10 *et seq*. (2018); and South

Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann. Regs. 61-92.280.20(a), (b), (c)(1)(i), (c)(1)(ii) (2018).

Summary: General Services Administration (Individual/Entity), owns and operates underground storage tanks located in Columbia, South Carolina. On April 15, 2019, the Department issued a Notice of Alleged Violation because the UST did not have corrosion protection, did not have spill protection, and did not have overfill prevention equipment. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to equip a permitted or upgraded steel tank and steel piping with corrosion protection; failed to equip a permitted or upgraded site with spill protection; and failed to equip a permitted or upgraded site with overfill prevention equipment. All violations have been corrected.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of three thousand dollars **($3,000.00)**.

3) Order Type and Number: Consent Order 19-0077-UST
Order Date: July 22, 2019
Individual/Entity: **Palmetto Propane, Fuels, and Ice, Inc.**
Facility: Kwik Karry
Location: 503 West Church Street
Batesburg, SC 29006
Mailing Address: 131 West Church Street
Batesburg, SC 29006
County: Lexington
Previous Orders: None
Permit/ID Number: 06003
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988, S.C. Code Ann. § 44-2-10 et seq. (2018) (SUPERB Act); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92, 280.41(b)(1)(i)(A)(2012 & Supp. 2018)

Summary: Palmetto Propane, Fuels, and Ice, Inc. (Individual/Entity) owns and operates underground storage tanks in Batesburg, South Carolina. On March 4, 2019, the Department issued a Notice of Alleged Violation because there was no automatic line leak detector equipped on the 8,000-gallon premium tank. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to equip a pressurized line with an automatic line leak detector. All violations have been corrected.

Action: The Individual/Entity is required to pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Solid Waste Enforcement

4) Order Type and Number: Consent Order 19-16-SW
Order Date: July 25, 2019
Individual/Entity: **Steve Henderson**
Facility: TMS #2-33-01-008.01
Location: 741 Jonas Circle
Chesnee, SC 29323
Mailing Address: 1201 Fish Camp Road
Chesnee, SC 29323
County: Spartanburg
Previous Orders: None
Permit/ID Number: N/A
Violations Cited: South Carolina Solid Waste Policy and Management Act of 1991, S.C. Code Ann. §§ 44-96-10 et seq. (2002 & Supp. 2016) and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation, R.61-107.19 (2012); Part II.B.1.

Summary: Steve Henderson (Individual/Entity), located in Chesnee, South Carolina, operated a structural fill without a permit from the Department. On September 20, 2018, October 15, 2018, November 30, 2018, and January 15, 2019, the Department observed a drainage ravine partially filled with land clearing debris. The Individual/Entity has violated the South Carolina Solid Waste Policy and Management Act and the Solid Waste Management: Solid Waste Landfills and Structural Fill Regulation, as follows: disposed of land-clearing debris without first obtaining a permit from the Department to operate a structural fill.

Action: The Individual/Entity is required to: submit a copy of a deed notation for the area of the property that was filled; pay a civil penalty in the amount of five hundred dollars **($500.00)**; and pay a suspended penalty in the amount of three thousand dollars ($3,000.00) should any requirement of the Order not be met.

Mining Enforcement

5) Order Type and Number: Consent Order 19-05-MSWM
Order Date: July 3, 2019
Individual/Entity: **Jason Deck**
Facility: Pacolet River Pit
Location: Intersection of Wilkie Bridge Road and Ray Blackley Road, northwest of Fingerville, SC
Mailing Address: 281 Canoe Drive
Mill Spring, NC 28756
County: Spartanburg
Previous Orders: None
Permit/ID Number: None
Violations Cited: South Carolina Mining Act S.C. Code Ann. 48-20-10 et seq. (Rev. 2008); South Carolina Mining Regulation (Supp. 2012), R.89-20.

Summary: Jason Deck (Individual/Entity), conducted unpermitted dredging activity in the North Pacolet River near Fingerville, South Carolina for a period of one year. On March 13, 2018, and March 21, 2019, the Department conducted inspections at the Facility. The Individual/Entity has violated the South Carolina Mining Act, and the South Carolina Mining Regulation as follows: failed to obtain a permit from the Department prior to obtaining a mine.

Action: The Individual/Entity is required to: cease all mining activity until appropriate mining permits are obtained or reclamation of the Facility is completed pay a civil penalty in the amount of one thousand dollars **($1,000.00).**

BUREAU OF WATER

Recreational Waters Enforcement

6) Order Type and Number: Consent Order 19-044-RW
Order Date: July 2, 2019
Individual/Entity: **The Townhomes of St. Andrews Woods Improvement Association, Inc.**
Facility: The Townhomes of St. Andrews Woods
Location: 100 Townhome Court
Columbia, SC 29210
Mailing Address: Same
County: Richland
Previous Orders: None
Permit/ID Number: 40-120-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)(22)

Summary: The Townhomes of St. Andrews Woods Improvement Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 7, 2019, the pool was inspected, and it was determined that the pool was in violation because it has been closed for a period in excess of twenty-four consecutive months and has not been filled in or removed. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to fill in or remove a pool, which has been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: make all required operational and maintenance upgrades to the pool to bring the pool into compliance, or properly fill in or remove the pool; and, pay a **stipulated penalty** in the amount of three hundred forty dollars (**$340.00**) should any requirement of the Order not be met.

7) Order Type and Number: Consent Order 19-045-RW
Order Date: July 3, 2019
Individual/Entity: **2600 North Homeowners' Association, Inc.**
Facility: Anderson Ocean Club
Location: 2600 North Ocean Boulevard

	Myrtle Beach, SC 29577
Mailing Address:	124 Highway 17 South North Myrtle Beach, SC 29582
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-1617D
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: 2600 North Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa. On May 23, 2019, and June 19, 2019, the spa was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

8)

Order Type and Number:	Consent Order 19-046-RW
Order Date:	July 15, 2019
Individual/Entity:	**Ambassador Villas Homeowners' Association, Inc.**
Facility:	Ambassador Villas
Location:	507 South Ocean Boulevard North Myrtle Beach, SC 29582
Mailing Address:	138 Woodland Drive Huntington, WV 25705
County:	Horry
Previous Orders:	None
Permit/ID Number:	26-1513D
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: Ambassador Villas Homeowners' Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa. On May 29, 2019, and June 17, 2019, the spa was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the spa temperature was too high; and, the spa rules sign was not completely filled out. On June 19, 2019, a follow-up inspection was conducted, and it was determined that all of the deficiencies had been addressed.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

9) Order Type and Number: Consent Order 19-047-RW
Order Date: July 15, 2019
Individual/Entity: **Summerville Lodge, Limited Partnership**
Facility: Days Inn by Wyndham St. George
Location: 139 Motel Drive
St. George, SC 29477
Mailing Address: Same
County: Dorchester
Previous Orders: None
Permit/ID Number: 18-071-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Summerville Lodge, Limited Partnership (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 28, 2019, and June 21, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the plaster on the pool floor was delaminated; there was a leak in the piping in the equipment room; the chlorine and pH levels were not within the acceptable range of water quality standards; only one "Shallow Water – No Diving Allowed" sign was posted; the "No Lifeguard On Duty – Swim At Your Own Risk" signs did not have the correct wording; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for review during the first inspection and was not maintained on a daily basis during the second inspection; a ladder was missing bumpers; the bathrooms were not clean and did not have paper towels or a hand dryer; the drinking water fountain was not operating properly; and, the life ring was deteriorated and the life ring rope was not the required length.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

10) Order Type and Number: Consent Order 19-048-RW
Order Date: July 15, 2019
Individual/Entity: **Chestnut Hill Mental Health Center, Inc.**
Facility: Springbrook Autism Behavioral Health
Location: 1 Havenwood Lane, Suite B
Travelers Rest, SC 29690
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit/ID Number: 23-327-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Chestnut Hill Mental Health Center, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On March 7, 2019, and June 17, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a handrail was missing a bolt cover; the chlorine and pH levels were not within the acceptable range

of water quality standards; a water line depth marker tile was broken; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

11) Order Type and Number: Consent Order 19-049-RW
Order Date: July 15, 2019
Individual/Entity: **Gold's Southeast, LLC**
Facility: Gold's Gym Cherrydale
Location: 3247 Worth Pleasantburg Drive
Greenville, SC 29609
Address: 10708 Kingston Pike
Knoxville, TN 37934
County: Greenville
Previous Orders: None
Permit/ID Number: 23-1202D
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Gold's Southeast, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa. On March 25, 2019, and June 13, 2019, the spa was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the spa temperature was not posted; and, the spa rules sign did not have all of the required rules.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

12) Order Type and Number: Consent Order 19-050-RW
Order Date: July 15, 2019
Individual/Entity: **WWT, LLC**
Facility: Sleep Inn Summerville
Location: 115 Holiday Drive
Summerville, SC 29483
Mailing Address: Same
County: Berkeley
Previous Orders: None
Permit/ID Number: 08-080-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: WWT, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 31, 2019, and June 24, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool walls were not clean; the pool equipment room was not accessible; a ladder was missing bumpers; a skimmer was missing a weir; the chlorine

level was not within the acceptable range of water quality standards; the pool rules sign was not completely filled out; the bound and numbered log book was not maintained on a daily basis; and, there were chlorine sticks in the skimmer baskets.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

13) Order Type and Number: Consent Order 19-051-RW
Order Date: July 15, 2019
Individual/Entity: **MC Suite, Inc.**
Facility: Comfort Suites
Location: 1025 Jockey Court
Summerville, SC 29483
Mailing Address: Same
County: Berkeley
Previous Orders: 14-133-DW ($1,600.00);
18-173-RW ($2,720.00)
Permit/ID Number: 08-1002B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: MC Suite, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 31, 2019, and June 24, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the drinking water fountain was not operating properly; the foot rinse shower was not operating properly; the gate did not self-close and latch; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the bound and numbered log book was not maintained on a daily basis; and, there were chlorine sticks in the skimmer baskets.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of two thousand seven hundred twenty dollars **($2,720.00)**.

14) Order Type and Number: Consent Order 19-052-RW
Order Date: July 18, 2019
Individual/Entity: **CDOR CHS Holiday, LLC**
Facility: Home 2 Suites
Location: 221 Holiday Drive
Summerville, SC 29483
Mailing Address: Same
County: Dorchester
Previous Orders: None
Permit/ID Number: 18-1067B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: CDOR CHS Holiday, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 31, 2019, and June 24, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was not tight and secure; a ladder was missing bumpers; skimmers were missing weirs; the drinking water fountain was not operating properly; the chlorine level was not within the acceptable range of water quality standards; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

15) Order Type and Number: Consent Order 19-053-RW
Order Date: July 22, 2019
Individual/Entity: **Charleston Southern University**
Facility: Charleston Southern University
Location: 9200 University Boulevard
Charleston, SC 29406
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-485-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Charleston Southern University (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 11, 2019, and July 3, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pool floor was dirty; a skimmer was missing a weir and a skimmer lid was cracked; the foot rinse shower was not operating properly; the chlorine and pH levels were not within the acceptable range of water quality standards; only one "No Lifeguard On Duty - Swim At Your Own Risk" sign was posted; and, the bound and numbered log book was not maintained on a daily basis and was not maintained a minimum of three times per week by the pool operator of record.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

16) Order Type and Number: Consent Order 19-054-RW
Order Date: July 22, 2019
Individual/Entity: **Mid-America Apartments, L.P.**
Facility: Farmington Village
Location: 2100 Farm Springs Road
Summerville, SC 29483
Mailing Address: Same
County: Dorchester
Previous Orders: None
Permit/ID Number: 18-1032B

Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Mid-America Apartments, L.P. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 3, 2019, and June 24, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was not tight and secure; a skimmer was missing a weir; and, the chlorine and pH levels were not within the acceptable range of water quality standards.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**.

17) Order Type and Number: Consent Order 19-055-RW
Order Date: July 26, 2019
Individual/Entity: **Upstate Property Rentals, LLC**
Facility: College Pointe Apartments
Location: 1200 Spartan Village
Spartanburg, SC 29303
Mailing Address: 514 North East Main Street
Simpsonville, SC 29681
County: Horry
Previous Orders: None
Permit/ID Number: 42-1033B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Upstate Property Rentals, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 28, 2019, and July 1, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a bolt cover was not secure; the flow meter was not operating; the chlorine and pH levels were not within the acceptable range of water quality standards; and, the gate did not self-close and latch.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

18) Order Type and Number: Consent Order 19-056-RW
Order Date: July 26, 2019
Individual/Entity: **Autumn Park Apartments, LLC**
Facility: Autumn Park Apartments
Location: 105 Turning Leaf Circle
Boiling Springs, SC 29316
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: 42-1004B & 42-1005D
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Autumn Park Apartments, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a spa. On May 28, 2019, and July 8, 2019, the pool and spa were inspected, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the flow meter was not operating; the chlorine level was not within the acceptable range of water quality standards; the emergency notification device was not operational; the bound and numbered log book was not maintained on a daily basis; the bound and numbered log book was not maintained a minimum of three times per week by the pool operator of record; a skimmer was missing a weir; the cyanuric acid level was not being recorded weekly in the bound and numbered log book; the waterline tiles were dirty; and, the bathrooms were missing paper towels and toilet paper.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of one thousand, three hundred sixty dollars **($1,360.00)**. The civil penalty has been paid.

19) Order Type and Number: Consent Order 19-057-RW
Order Date: July 26, 2019
Individual/Entity: **Plantation Point Horizontal Property Regime Owners Association, Inc.**
Facility: Plantation Point
Location: 897 Fording Island Road
Bluffton, SC 29910
Mailing Address: Same
County: Beaufort
Previous Orders: None
Permit/ID Number: 07-510-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Plantation Point Horizontal Property Regime Owners Association, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 7, 2019, and July 11, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the pH level was not within the acceptable range of water quality standards; there were no "Shallow Water – No Diving Allowed" signs posted; the current pool operator of record information was not posted to the public; the bound and numbered log book was not available for Department review on the first inspection; and, the bound and numbered log book was not maintained on a daily basis on the second inspection.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

20) Order Type and Number: Consent Order 19-058-RW
Order Date: July 26, 2019
Individual/Entity: **LCOF Myrtle Beach Investment, LLC**
Facility: Best Western Grand Strand
Location: 1804 South Ocean Boulevard
Myrtle Beach, SC 29577

Mailing Address: Same
County: Horry
Previous Orders: None
Permit/ID Number: 26-1429B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: LCOF Myrtle Beach Investment, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 28, 2019, and June 24, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; only one "No Lifeguard On Duty – Swim At Your Own Risk" sign was posted; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

21) Order Type and Number: Consent Order 19-059-RW
Order Date: July 26, 2019
Individual/Entity: **Charleston Southern University**
Facility: Wingate Inn
Location: 9280 University Boulevard
North Charleston, SC 29406
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1166B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Charleston Southern University (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 11, 2019, and July 3, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a skimmer was missing a weir; the chlorine and pH levels were not within the acceptable range of water quality standards; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

22) Order Type and Number: Consent Order 19-060-RW
Order Date: July 26, 2019
Individual/Entity: **Planters Retreat, LLC**
Facility: Planters Retreat
Location: 4370 Ladson Road
Ladson, SC 29456
Mailing Address: Same

County: Dorchester
Previous Orders: None
Permit/ID Number: 18-1030B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Planters Retreat, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 5, 2019, and July 1, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; a skimmer was missing a weir; the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; the bound and numbered log book was not maintained on a daily basis; and, there were chlorine sticks in the skimmer baskets.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

23) Order Type and Number: Consent Order 19-061-RW
Order Date: July 30, 2019
Individual/Entity: **G6 Hospitality Property, LLC**
Facility: Motel 6 Charleston North SC
Location: 2551 Ashley Phosphate Road
North Charleston, SC 29418
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-365-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: G6 Hospitality Property, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 5, 2019, and June 27, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder was missing bumpers; the life ring did not have a permanently attached rope; the pool rules sign did not have all of the required rules; the "Shallow Water – No Diving Allowed" signs were obstructed on the first inspection, and only one "Shallow Water – No Diving Allowed" sign was posted on the second inspection; the "No Lifeguard On Duty - Swim At Your Own Risk" signs did not have the correct wording on the first inspection, and only one "No Lifeguard On Duty - Swim At Your Own Risk" sign was posted on the second inspection; and, the chlorine and pH levels were not within the acceptable range of water quality standards.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

24) Order Type and Number: Consent Order 19-062-RW
Order Date: July 26, 2019
Individual/Entity: **Tulsi, Inc.**
Facility: Days Inn by Wyndham Spartanburg
Location: 115 Rogers Commerce Boulevard
Spartanburg, SC 29316
Mailing Address: Same
County: Spartanburg
Previous Orders: None
Permit/ID Number: 42-192-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Tulsi, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On May 31, 2019, and July 11, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a ladder and handrail were not tight and secure; a ladder was missing non-slip tread inserts; a bolt cover was in disrepair; the pH level was not within the acceptable range of water quality standards; only one "Shallow Water – No Diving Allowed" sign was posted and the sign posted did not have the correct wording or the correct size lettering; the "No Lifeguard On Duty - Swim At Your Own Risk" signs did not have the correct wording or the correct size lettering; the pool rules sign did not have all of the required rules; waterline tiles were broken; step edge tiles were missing; the cyanuric acid level was not checked weekly; and, the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

25) Order Type and Number: Consent Order 19-063-RW
Order Date: July 26, 2019
Individual/Entity: **Brothers Property Management Corporation**
Facility: Charleston Harbor Resort & Marina Hotel
Location: 20 Patriots Point Road
Mount Pleasant, SC 29464
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit/ID Number: 10-1260D
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Brothers Property Management Corporation (Individual/Entity) owns and is responsible for the proper operation and maintenance of a spa. On May 29, 2019, and June 21, 2019, the spa was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the chlorine and pH levels were not within the acceptable range of water quality standards; the cyanuric acid level was above the water quality standards acceptable limit; and, the emergency notification device was not operational.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

26) Order Type and Number: Consent Order 19-064-RW
Order Date: July 26, 2019
Individual/Entity: **Bluffton Hotels, LLC**
Facility: Comfort Suites
Location: 23 Town Drive
Bluffton, SC 29910
Mailing Address: Same
County: Beaufort
Previous Orders: None
Permit/ID Number: 07-1064B
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Bluffton Hotels, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 7, 2019, and July 11, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: a light in the pool wall was out of its niche; the chlorine level was not within the acceptable range of water quality standards; only one "Shallow Water – No Diving Allowed" sign was posted; the "No Lifeguard On Duty – Swim At Your Own Risk" signs did not have the correct wording and did not have the correct size lettering; the current pool operator of record information was not posted to the public; and the bound and numbered log book was not maintained on a daily basis.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

27) Order Type and Number: Consent Order 19-065-RW
Order Date: July 30, 2019
Individual/Entity: **Baynard Cove Villas Regime, Inc.**
Facility: Baynard Cove Villas
Location: 1040 William Hilton Parkway
Hilton Head, SC 29928
Mailing Address: Same
County: Beaufort
Previous Orders: None
Permit/ID Number: 07-029-1
Violations Cited: S.C. Code Ann. Regs. 61-51(J)

Summary: Baynard Cove Villas Regime, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool. On June 3, 2019, and July 5, 2019, the pool was inspected, and a violation was issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the lifeline floats

were damaged; algae was present on the walls of the pool; skimmers were missing weirs; and, the chlorine and pH levels were not within the acceptable range of water quality standards.

Action: The Individual/Entity is required to: pay a civil penalty in the amount of six hundred eighty dollars **($680.00)**. The civil penalty has been paid.

Drinking Water Enforcement

28) Order Type and Number: Consent Order 19-013-DW
Order Date: July 2, 2019
Individual/Entity: **Meansville-Riley Road Water Company, Inc.**
Facility: Meansville Riley Water District
Location: 1779 Cross Keys Highway
Buffalo, SC 29321
Mailing Address: P.O. Box 823
Union, SC 29379
County: Union
Previous Orders: None
Permit/ID Number: 4420001
Violations Cited: S.C. Code Ann. Regs. 61-58.17.K(1)(a), 61-58.6.E(2)(b)(i), and 61-58.6.E(2)(c)

Summary: Meansville-Riley Road Water Company, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS). On May 13, 2019, a violation was issued as a result of review of monitoring records; and, a violation was issued for failure to provide public notice. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS tested present for total coliform and E. coli, which resulted in a violation of the maximum contaminant level (MCL) for E. coli; and, the Individual/Entity failed to provide public notice as soon as practical, but no later than twenty-four hours after learning of the violation in a form and manner reasonably calculated to reach all persons served.

Action: The Individual/Entity is required to: submit a standard operating procedure to ensure that all public notice requirements are complied with; submit a corrective action plan to include proposed steps to address the MCL violation; pay a civil penalty in the amount of three thousand dollars **($3,000.00)**; and, pay a stipulated penalty in the amount of four thousand dollars ($4,000.00) should any requirement of the Order not be met.

29) Order Type and Number: Consent Order 19-014-DW
Order Date: July 2, 2019
Individual/Entity: **Carbon Construction, LLC**
Facility: Governors Landing Phase 1
Location: 1515 Edgefield Road
North Augusta, SC 29860
Mailing Address: P.O. Box 1268
Evans, GA 30809
County: Edgefield

Previous Orders: None
Permit/ID Number: 33555-WS
Violations Cited: S.C. Code Ann. Regs. 61-58.1.B

Summary: Carbon Construction, LLC (Individual/Entity) owns and is responsible for the proper construction and installation of a drinking water distribution system to serve Governors Landing Phase 1 (Site). On May 13, 2019, Department staff determined that a drinking water distribution system had been constructed at the Site and a permit to construct had not been issued by the Department. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: failure to obtain a permit to construct from the Department prior to the construction of a drinking water distribution system.

Action: The Individual/Entity is required to: submit a standard operating procedure to ensure that all future permitting requirements are complied with; and, pay a civil penalty in the amount of two thousand dollars **($2,000.00)**.

30) Order Type and Number: Consent Order 19-015-DW
Order Date: July 2, 2019
Individual/Entity: Town of Hemingway
Facility: Town of Hemingway
Location: 110 South Main Street
Hemingway, SC 29554
Mailing Address: Same
County: Williamsburg
Previous Orders: 15-041-DW ($4,000.00 stipulated)
Permit/ID Number: 4510004
Violations Cited: S.C. Code Ann. Regs. 61-58.5.P(2)(b)

Summary: The Town of Hemingway (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS). On April 10, 2019, a violation was issued as a result of review of monitoring records. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: the PWS exceeded the maximum contaminant level (MCL) for total trihalomethanes.

Action: The Individual/Entity is required to: submit a corrective action plan to include proposed steps to address the MCL violation; and, pay a **stipulated penalty** in the amount of four thousand dollars **($4,000.00)** should any requirement of the Order not be met.

31) Order Type and Number: Consent Order 19-016-DW
Order Date: July 2, 2019
Individual/Entity: **City of Denmark**
Facility: City of Denmark
Location: 4768 Carolina Highway
Denmark, SC 29042
Mailing Address: Same
County: Bamberg

Previous Orders: None
Permit/ID Number: 0510002
Violations Cited: S.C. Code Ann. Regs. 61-58.7

Summary: The City of Denmark (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS). On April 2, 2019, the PWS was inspected and rated unsatisfactory for failure to properly operate and maintain. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: some of the backflow prevention devices had not been tested in 2018 and 2019, and there was no replacement schedule for non-testable devices; malfunctional hydrants identified during fire flow testing in November and December 2018 had not been repaired or replaced; a complete flushing program had not been developed and implemented; a plan had not been submitted to address recommendations from the April 2018 and March 29, 2019, elevated storage tank inspection reports for the Voorhees and Nibco tanks; and a plan and schedule had not been submitted to address maintenance deficiencies of the Bamberg County Industrial Park elevated storage tank, and the tank had not been incorporated into the PWS's operating procedures.

Action: The Individual/Entity is required to: valve off the Bamberg County Industrial Park elevated storage tank from the distribution system; submit a written request for intended use of Well 4 Cox Mill Well; properly abandon Well 1 Booker Center and Well 3 Legare Street Wells; survey the PWS to identify all cross connections and ensure proper backflow prevention devices are installed, tested, and added to the inventory for annual testing; submit an updated valve and hydrant maintenance program and repair/replace all malfunctional hydrants; submit an updated system map; submit a revised procedures manual with updated programs to accurately reflect the current configuration of the PWS; complete all repairs to the Voorhees and Nibco elevated storage tanks per the March 29, 2019, inspection reports; and, pay a civil penalty in the amount of four thousand dollars **($4,000.00)**.

Water Pollution Enforcement

32) Order Type and Number: Consent Order 19-043-W
Order Date: July 2, 2019
Individual/Entity: **Welby's Construction Materials, LLC**
Facility: Coldwater Mine/Powder Horn Mine
Location: Smoak Road/Grant Road
Dorchester, SC 29437
Mailing Address: P.O. Box 368
Summerville, SC 29484
County: Dorchester
Previous Orders: None
Permit/ID Number: NPDES Permits SCG730853 & SCG731428
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1- 110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) and (d) (2011).

Summary: Welby's Construction Materials, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of two mines located in Dorchester County, South

Carolina. On October 24, 2018, a Notice of Violation was issued as a result of violations of the permitted discharge limits for pH as reported on discharge monitoring reports submitted to the Department for the May 2018 through August 2018 monthly reporting periods (Coldwater Mine) and the January 2018 through September 2018 reporting periods (Powder Horn Mine). The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent discharge limits of its National Pollutant Discharge Elimination System permit for pH.

Action: The Individual/Entity is required to: submit to the Department a corrective action plan (CAP) addressing the deficiencies; and, pay a civil penalty in the amount of four thousand dollars **($4,000.00).**

33) Order Type and Number: Consent Order 19-044-W
Order Date: July 2, 2019
Individual/Entity: **Granite Rolling Meadows, LLC**
Facility: Rolling Meadows Mobile Home Community
Location: 3941 Charleston Highway
West Columbia, SC 29172
Mailing Address: 175 Precipice Road
Camden, SC 29020
County: Lexington
Previous Orders: None
Permit/ID Number: NPDES Permit SC0033685
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1- 110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.21(d) (2011).

Summary: Granite Rolling Meadows, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Lexington County, South Carolina. On May 14, 2019, a Notice of Violation was issued as a result of reporting requirement violations of the National Pollutant Discharge Elimination System (NPDES) permit. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to submit permit re-application 180 days before the existing permit expires.

Action: The Individual/Entity is required to: submit an administratively complete application for renewal of its NPDES permit; continue operation of its WWTF in accordance with the current NPDES permit until a new permit becomes effective; and, pay a civil penalty in the amount of one thousand dollars **($1,000.00).**

34) Order Type and Number: Consent Order 19-045-W
Order Date: July 9, 2019
Individual/Entity: **South Forge L.P.**
Facility: South Forge Apartments
Location: 230 Highway 261 South
Wedgefield, SC 29168

Mailing Address: 1230 Folly Road
Charleston, SC 29412
County: Sumter
Previous Orders: None
Permit/ID Number: NPDES Permit SC0033235
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1- 110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41(a) (2011).

Summary: South Forge L.P. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) located in Sumter County, South Carolina. On March 5, 2019, a Notice of Violation was issued as a result of violations of the permitted discharge limits for total copper (TC) as reported on Discharge Monitoring Reports submitted to the Department for the quarterly monitoring periods ending September 30, 2018, and December 31, 2018. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent discharge limits of the National Pollutant Discharge Elimination System Permit for TC.

Action: The Individual/Entity is required to: submit to the Department a corrective action plan (CAP) addressing the deficiencies; and, pay a civil penalty in the amount of three thousand, four hundred dollars **($3,400.00).**

35) Order Type and Number: Consent Order 19-046-W
Order Date: July 22, 2019
Individual/Entity: **Pilgrim's Pride Corporation**
Facility: Sumter Poultry Processing Facility WWTF
Location: 2050 Highway 15 South
Sumter County, SC
Mailing Address: 2050 HWY 15 South
Sumter, SC 29150
County: Sumter
Previous Orders: None
Permit/ID Number: NPDES Permit SC0000795
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1- 110 (d) (2008 & Supp. 2018); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.122.41 (a) (2011).

Summary: Pilgrim's Pride Corporation (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) serving its poultry processing plant located in Sumter County, South Carolina. On December 20, 2018, a Notice of Violation was issued to the Individual/Entity as a result of violations of the permitted discharge limits for chronic effluent toxicity (CTOX) as reported on Discharge Monitoring Reports submitted to the Department for the monitoring periods ending October 31, 2018, and February 28, 2019. The Individual/Entity has violated the Pollution Control Act and Water Pollution Control Permits Regulation as follows: failed to comply with the effluent discharge limits of its National Pollutant Discharge Elimination System permit (NPDES) for CTOX.

Action: The Individual/Entity is required to: submit to the Department a corrective action plan (CAP) addressing the deficiencies; monitor for CTOX for one year following the final implementation of the CAP; conduct a Toxicity Identification Evaluation/Toxicity Reduction Evaluation in the event of failure to meet CTOX limits within the year following final implementation of the CAP; submit quarterly progress reports; and, pay a civil penalty in the amount of two thousand, eight hundred dollars **($2,800.00).**

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

36) Order Type and Number: Administrative Order 2019-206-03-005
Order Date: July 12, 2019
Individual/Entity: **Edward Southworth**
Facility: Fast Eddies Calzones
Location: 817 Harden Street
Columbia, SC 29205
Mailing Address: Same
County: Richland
Previous Orders: 2015-206-03-122 ($800.00)
Permit Number: 40-206-07266
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Fast Eddies Calzones (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on July 5, 2018, August 10, 2018, August 22, 2018, December 5, 2018, December 14, 2018, December 19, 2018, January 14, 2019, January 24, 2019, and February 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep food contact surfaces, nonfood contact surfaces, and utensils clean and free of accumulation of dust, dirt, food residue, and other debris.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of three thousand, five hundred dollars **($3,500.00)**.

37) Order Type and Number: Administrative Order 2019-206-02-014
Order Date: July 29, 2019
Individual/Entity: **Joe Caradonna**
Facility: Caviar & Bananas
Location: 1 North Laurens Street
Greenville, SC 29601
Mailing Address: 51 George Street
Charleston, SC 29401
County: Greenville
Previous Orders: 2018-206-02-036 ($800.00)
Permit Number: 23-206-11456

Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Caviar & Bananas (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on May 31, 2018, June 7, 2018, and January 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; failed to clearly mark the date by which food shall be consumed on the premises, sold, or discarded when held at a temperature of 41°F or less for a maximum of seven (7) days; and failed to ensure that when ready-to-eat foods exceed the date mark, or ready-to-eat foods are found without the required date mark, foods were properly discarded. This applies only to refrigerated, ready-to-eat, time/temperature control for safety foods prepared and held in a food establishment for more than twenty-four (24) hours.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

38) Order Type and Number: Consent Order 2019-206-01-031
Order Date: July 1, 2019
Individual/Entity: **China Inn**
Facility: China Inn
Location: 506 Bypass 123
Seneca, SC 29678
Mailing Address: Same
County: Oconee
Previous Orders: None
Permit Number: 37-206-01263
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: China Inn (Individual/Entity) is a restaurant located in Seneca, South Carolina. The Department conducted inspections on June 30, 2017, May 16, 2018, and April 23, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

39) Order Type and Number: Consent Order 2019-206-02-023
Order Date: July 1, 2019
Individual/Entity: **Gringo's**
Facility: Gringo's
Location: 11 West Camperdown Way
Greenville, SC 29601
Mailing Address: Same

County: Greenville
Previous Orders: 2018-206-02-034 ($800.00)
Permit Number: 23-206-10777
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Gringo's (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on August 28, 2017, May 23, 2018, and February 26, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

40) Order Type and Number: Consent Order 2019-206-02-030
Order Date: July 1, 2019
Individual/Entity: **The Alumni and Bar 101**
Facility: The Alumni and Bar 101
Location: 1310 Tiger Boulevard
Clemson, SC 29631
Mailing Address: 1 Hawks Perchway
Simpsonville, SC 29681
County: Pickens
Previous Orders: None
Permit Number: 39-206-01997
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: The Alumni and Bar 101 (Individual/Entity) is a restaurant located in Clemson, South Carolina. The Department conducted inspections on June 5, 2017, May 14, 2018, and April 1, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

41) Order Type and Number: Consent Order 2019-206-02-038
Order Date: July 1, 2019
Individual/Entity: **Vic's Pizza**
Facility: Vic's Pizza
Location: 12 East Coffee Street
Greenville, SC 29601
Mailing Address: Same
County: Greenville

Previous Orders: 2017-206-02-037 ($800.00);
2019-206-02-012 ($1,000.00)
Permit Number: 23-206-11285
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Vic's Pizza (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on February 8, 2018, December 12, 2018, and May 1, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep food contact surfaces, nonfood contact surfaces, and utensils clean and free of accumulation of dust, dirt, food residue, and other debris.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two hundred fifty dollars **($250.00)**.

42) Order Type and Number: Consent Order 2019-206-03-055
Order Date: July 1, 2019
Individual/Entity: **Chili's Grill & Bar**
Facility: Chili's Grill & Bar
Location: 295 Ginny Lane
Lexington, SC 29072
Mailing Address: 2280 Highland Village Road, Suite 150
Lewisville, TX 75077
County: Lexington
Previous Orders: None
Permit Number: 32-206-05419
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Chili's Grill & Bar (Individual/Entity) is a restaurant located in Lexington, South Carolina. The Department conducted inspections on April 20, 2017, April 6, 2018, April 3, 2019, April 12, 2019, and April 22, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods and failed to ensure that physical facilities were maintained in good repair.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, two hundred dollars **($1,200.00)**.

43) Order Type and Number: Consent Order 2019-206-03-058
Order Date: July 1, 2019
Individual/Entity: **Jin's Hibachi & Chinese**
Facility: Jin's Hibachi & Chinese
Location: 4435 Hardscrabble Road
Columbia, SC 29229
Mailing Address: Same

County: Richland
Previous Orders: 2016-206-03-009 ($800.00)
Permit Number: 40-206-07419
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Jin's Hibachi & Chinese (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on March 29, 2018, May 24, 2018, and May 21, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

44) Order Type and Number: Consent Order 2019-206-04-019
Order Date: July 1, 2019
Individual/Entity: **Savway**
Facility: Savway
Location: 300 Ron McNair Boulevard
Lake City, SC 29560
Mailing Address: Same
County: Florence
Previous Orders: None
Permit Number: 21-206-02514
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Savway (Individual/Entity) is a convenience store located in Lake City, South Carolina. The Department conducted inspections on April 25, 2018, January 28, 2019, February 21, 2019, March 1, 2019, March 11, 2019, and March 21, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of three thousand, two hundred dollars **($3,200.00)**.

45) Order Type and Number: Consent Order 2019-206-04-022
Order Date: July 1, 2019
Individual/Entity: **Outback Steakhouse #4119**
Facility: Outback Steakhouse #4119
Location: 110 Dunbarton Drive
Florence, SC 29501
Mailing Address: 2202 N. West Shore Boulevard, 5th Floor
Tampa, FL 33607
County: Florence

Previous Orders: None
Permit Number: 21-206-01165
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Outback Steakhouse #4119 (Individual/Entity) is a restaurant located in Florence, South Carolina. The Department conducted inspections on January 10, 2018, November 26, 2018, and April 10, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

46) Order Type and Number: Consent Order 2019-206-05-008
Order Date: July 1, 2019
Individual/Entity: **Dixie Riverside Inc.**
Facility: Dixie Riverside Inc.
Location: 246 Old Jackson Highway
Beech Island, SC 29842
Mailing Address: 2719 Mike Padgett Highway
Augusta, GA 30906
County: Aiken
Previous Orders: None
Permit Number: 02-206-02501
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Dixie Riverside Inc. (Individual/Entity) is a restaurant located in Beech Island, South Carolina. The Department conducted inspections on September 6, 2018, April 24, 2019, and May 2, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

47) Order Type and Number: Consent Order 2019-206-05-009
Order Date: July 1, 2019
Individual/Entity: **La Jalisciense**
Facility: La Jalisciense
Location: 535 Old Edgefield Road
North Augusta, SC 29841
Mailing Address: Same
County: Aiken
Previous Orders: None
Permit Number: 02-206-02862

Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: La Jalisciense (Individual/Entity) is a restaurant located in North Augusta, South Carolina. The Department conducted inspections on July 12, 2018, October 30, 2018, and April 16, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

48) Order Type and Number: Consent Order 2019-206-06-058
Order Date: July 1, 2019
Individual/Entity: **Denny's**
Facility: Denny's
Location: 730 Highway 17 South
North Myrtle Beach, SC 29582
Mailing Address: 2160 Scenic Highway North
Snellville, GA 30078
County: Horry
Previous Orders: None
Permit Number: 26-206-13733
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Denny's (Individual/Entity) is a restaurant located in North Myrtle Beach, South Carolina. The Department conducted inspections on May 30, 2018, November 28, 2018, December 6, 2018, December 12, 2018, March 25, 2019, and April 4, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep food contact surfaces, nonfood contact surfaces, and utensils clean and free of accumulation of dust, dirt, food residue, and other debris and failed to clean the physical facilities as often as necessary to keep them clean.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

49) Order Type and Number: Consent Order 2019-206-06-067
Order Date: July 1, 2019
Individual/Entity: **American Legion 178**
Facility: American Legion 178
Location: 3950 Highway 17 Business
Murrells Inlet, SC 29576
Mailing Address: P.O. Box 478
Murrells Inlet, SC 29576
County: Georgetown

Previous Orders: None
Permit Number: N/A
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: American Legion 178 (Individual/Entity) is a restaurant located in Murrells Inlet, South Carolina. The Department conducted inspections on May 30, 2018, and May 16, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: provided food to the public without a valid permit issued by the Department.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two thousand dollars **($2,000.00)**.

50) Order Type and Number: Consent Order 2019-206-06-068
Order Date: July 1, 2019
Individual/Entity: **Wicked Tuna**
Facility: Wicked Tuna
Location: 4123 Highway 17 Business
Murrells Inlet, SC 29576
Mailing Address: Same
County: Georgetown
Previous Orders: 2016-206-06-087 ($800.00);
2017-206-06-030 ($1,200.00);
2017-206-06-129 ($1,000.00);
2018-206-06-070 ($1,000.00)
Permit Number: 22-206-06214
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Wicked Tuna (Individual/Entity) is a restaurant located in Murrells Inlet, South Carolina. The Department conducted inspections on May 7, 2019, and May 17, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two thousand dollars **($2,000.00)**.

51) Order Type and Number: Consent Order 2019-206-06-069
Order Date: July 1, 2019
Individual/Entity: **King Street Grille**
Facility: King Street Grille
Location: 3040 Howard Avenue
Myrtle Beach, SC 29577
Mailing Address: P.O. Box 30429
Charleston, SC 29417
County: Horry

Previous Orders: 2018-206-06-138 ($200.00);
2019-206-06-029 ($1,250.00)
Permit Number: 26-206-11152
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: King Street Grille (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted an inspection on May 1, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

52) Order Type and Number: Consent Order 2019-206-06-080
Order Date: July 1, 2019
Individual/Entity: **Jade Hibachi**
Facility: Jade Hibachi
Location: 201 Graduate Road
Conway, SC 29526
Mailing Address: 104 Jessica Lakes Drive
Conway, SC 29526
County: Horry
Previous Orders: 2016-206-06-131 ($1,200.00);
2018-206-06-125 ($2,000.00);
2019-206-06-044 ($1,250.00)
Permit Number: 26-206-10472
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Jade Hibachi (Individual/Entity) is a restaurant located in Conway, South Carolina. The Department conducted an inspection on May 23, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded; failed to keep food contact surfaces, nonfood contact surfaces, and utensils clean and free of accumulation of dust, dirt, food residue, and other debris; and failed to clean the physical facilities as often as necessary to keep them clean.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, two hundred fifty dollars **($1,250.00)**.

53) Order Type and Number: Consent Order 2019-206-07-028
Order Date: July 1, 2019
Individual/Entity: **Taco Loco**
Facility: Taco Loco
Location: 1000 Tanner Ford Boulevard, Suite 280

	North Charleston, SC 29410
Mailing Address:	Same
County:	Berkeley
Previous Orders:	None
Permit Number:	08-206-10683
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Taco Loco (Individual/Entity) is a restaurant located in North Charleston, South Carolina. The Department conducted inspections on May 1, 2017, April 9, 2018, and March 5, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods and failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

54)

Order Type and Number:	Consent Order 2019-206-07-035
Order Date:	July 1, 2019
Individual/Entity:	**Juanita Greenbergs**
Facility:	Juanita Greenbergs
Location:	410 West Coleman Boulevard
	Mount Pleasant, SC 29464
Mailing Address:	P.O. Box 21103
	Charleston, SC 29413
County:	Charleston
Previous Orders:	None
Permit Number:	10-206-07837
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Juanita Greenbergs (Individual/Entity) is a restaurant located in Mount Pleasant, South Carolina. The Department conducted inspections on October 10, 2017, October 4, 2018, and April 11, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

55)

Order Type and Number:	Consent Order 2019-206-07-050
Order Date:	July 1, 2019
Individual/Entity:	**Pad Thai I**
Facility:	Pad Thai I
Location:	119 West Doty Street

	Summerville, SC 29483
Mailing Address:	1818 Chickasaw Drive Charleston, SC 29414
County:	Dorchester
Previous Orders:	None
Permit Number:	18-206-08359
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Pad Thai I (Individual/Entity) is a restaurant located in Summerville, South Carolina. The Department conducted inspections on May 7, 2018, May 1, 2019, and May 9, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to provide a test kit or other device that accurately measures the concentration of MG/L of sanitizing solutions.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of four hundred dollars **($400.00)**.

56)

Order Type and Number:	Consent Order 2019-211-06-002
Order Date:	July 1, 2019
Individual/Entity:	**Mi Mexico**
Facility:	Mi Mexico
Location:	3839 Socastee Boulevard, Unit C Myrtle Beach, SC 29588
Mailing Address:	Same
County:	Horry
Previous Orders:	2019-211-06-001 ($1,200.00)
Permit Number:	26-211-10465
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Mi Mexico (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on October 25, 2018, February 15, 2019, and April 15, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

57)

Order Type and Number:	Consent Order 2019-206-01-033
Order Date:	July 8, 2019
Individual/Entity:	**Aramark/Lander Cafeteria**
Facility:	Aramark/ Lander Cafeteria
Location:	320 Stanley Avenue Greenwood, SC 29649

Mailing Address: Same
County: Greenwood
Previous Orders: None
Permit Number: 24-206-01488
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Aramark/ Lander Cafeteria (Individual/Entity) is a restaurant located in Greenwood, South Carolina. The Department conducted inspections on April 26, 2017, October 4, 2017, September 19, 2018, and May 22, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

58) Order Type and Number: Consent Order 2019-206-02-042
Order Date: July 8, 2019
Individual/Entity: **Church's Chicken**
Facility: Church's Chicken
Location: 880 North Church Street
Spartanburg, SC 29303
Mailing Address: 980 Hammond Drive, Suite 1100
Atlanta, GA 30328
County: Spartanburg
Previous Orders: None
Permit Number: 42-206-06633
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Church's Chicken (Individual/Entity) is a restaurant located in Spartanburg, South Carolina. The Department conducted inspections on August 3, 2018, January 3, 2019, April 3, 2019, April 12, 2019, and May 9, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep food contact surfaces, nonfood contact surfaces, and utensils clean and free of accumulation of dust, dirt, food residue, and other debris; failed to ensure that physical facilities were maintained in good repair; and failed to store poisonous or toxic materials so that they cannot contaminate food equipment, utensils, linens, and single-service and single-use articles.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, two hundred dollars **($1,200.00)**.

59) Order Type and Number: Consent Order 2019-206-03-65
Order Date: July 8, 2019
Individual/Entity: **Enmark #858**
Facility: Enmark #858
Location: 3860 Highway 378
Leesville, SC 29070
Mailing Address: P.O. Box 728
Savannah, GA 31402
County: Lexington
Previous Orders: None
Permit Number: 32-206-06301
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Enmark #858 (Individual/Entity) is a restaurant located in Leesville, South Carolina. The Department conducted inspections on January 12, 2018, June 7, 2018, and May 30, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues and failed to clean the physical facilities as often as necessary to keep them clean.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two hundred dollars **($200.00)**.

60) Order Type and Number: Consent Order 2019-206-04-021
Order Date: July 8, 2019
Individual/Entity: **Subway**
Facility: Subway
Location: 2884 North Williston Road
Florence, SC 29506
Mailing Address: 204 Amesbury Pointe
Florence, SC 29501
County: Florence
Previous Orders: None
Permit Number: 21-206-02654
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Subway (Individual/Entity) is a restaurant located in Florence, South Carolina. The Department conducted inspections on June 20, 2017, May 15, 2018, April 10, 2019, and April 17, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods and failed to ensure that after cleaning and sanitizing, equipment and utensils were properly air-dried before contact with food and may not be cloth dried.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of nine hundred dollars **($900.00)**.

61) Order Type and Number: Consent Order 2019-206-04-023
Order Date: July 8, 2019
Individual/Entity: **Little Caesar's Pizza**
Facility: Little Caesar's Pizza
Location: 1725 West Palmetto Street
Florence, SC 29501
Mailing Address: Same
County: Florence
Previous Orders: None
Permit Number: 21-206-02205
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Little Caesar's Pizza (Individual/Entity) is a restaurant located in Florence, South Carolina. The Department conducted inspections on May 7, 2018, April 1, 2019, and April 11, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to comply with the hazard analysis and critical control points (HACCP) plan and procedures that are submitted and approved as a basis for the modification or waiver; and maintain and provide to the Department, upon request, records that demonstrate the HACCP plan is being employed.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

62) Order Type and Number: Consent Order 2019-206-04-025
Order Date: July 8, 2019
Individual/Entity: **Country Cash & Carry**
Facility: Country Cash & Carry
Location: 2705 Highway 381
Clio, SC 29525
Mailing Address: 1902 Sherbrooke Circle
Laurinburg, NC 28352
County: Marlboro
Previous Orders: None
Permit Number: 34-206-00669
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Country Cash & Carry (Individual/Entity) is a convenience store located in Clio, South Carolina. The Department conducted inspections on October 18, 2018, October 26, 2018, and April 16, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

63) Order Type and Number: Consent Order 2019-206-06-054
Order Date: July 8, 2019
Individual/Entity: **Bellagio Italian Restaurant**
Facility: Bellagio Italian Restaurant
Location: 3550 Old Kings Highway
Murrells Inlet, SC 29576
Mailing Address: 2420 Summer Haven Loop
Conway, SC 29527
County: Georgetown
Previous Orders: 2018-206-06-166 ($1,500.00)
Permit Number: 22-206-06096
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Bellagio Italian Restaurant (Individual/Entity) is a restaurant located in Murrells Inlet, South Carolina. The Department conducted inspections on August 13, 2018, December 18, 2018, and April 17, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of five hundred dollars **($500.00)**.

64) Order Type and Number: Consent Order 2019-206-06-059
Order Date: July 8, 2019
Individual/Entity: **Sharkey's Beach Club**
Facility: Sharkey's Beach Club
Location: 600 North Ocean Boulevard
Myrtle Beach, SC 29577
Mailing Address: P.O. Box 2506
Myrtle Beach, SC 29578
County: Horry
Previous Orders: 2017-206-06-093 ($800.00);
2018-206-06-148 ($1,000.00)
Permit Number: 26-206-12417
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Sharkey's Beach Club (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on August 29, 2018, November 1, 2018, and April 25, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to protect food from contamination by storing in a clean, dry location, where it is not exposed to splash, dust, or other contamination, at least 6 inches above the floor and failed to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two hundred fifty dollars **($250.00)**.

65) Order Type and Number: Consent Order 2019-206-06-061
Order Date: July 8, 2019
Individual/Entity: **Hog Heaven**
Facility: Hog Heaven
Location: 7147 Ocean Highway
Pawleys Island, SC 29585
Mailing Address: Same
County: Georgetown
Previous Orders: None
Permit Number: 22-206-05542
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Hog Heaven (Individual/Entity) is a restaurant located in Pawleys Island, South Carolina. The Department conducted inspections on March 13, 2017, September 28, 2017, June 14, 2018, and April 26, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

66) Order Type and Number: Consent Order 2019-206-06-063
Order Date: July 8, 2019
Individual/Entity: **On the ½ Shell**
Facility: On the ½ Shell
Location: 4500 Highway 17 Bypass
Murrells Inlet, SC 29576
Mailing Address: Same
County: Georgetown
Previous Orders: 2016-206-06-141 ($800.00)
Permit Number: 22-206-05954
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: On the ½ Shell (Individual/Entity) is a restaurant located in Murrells Inlet, South Carolina. The Department conducted inspections on January 23, 2018, October 17, 2018, and April 23, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep shellstock tags or labels attached to the container in which the shellstock are received, until the container is empty.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of five hundred dollars **($500.00)**.

67) Order Type and Number: Consent Order 2019-206-06-075
Order Date: July 8, 2019
Individual/Entity: **CW's Wing and Rib Shack**
Facility: CW's Wing and Rib Shack
Location: 117 A Rivertown Boulevard
Conway, SC 29526
Mailing Address: Same
County: Horry
Previous Orders: 2019-206-06-030 ($200.00)
Permit Number: 26-206-13105
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: CW's Wing and Rib Shack (Individual/Entity) is a restaurant located in Conway, South Carolina. The Department conducted an inspection on May 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep food contact surfaces, nonfood contact surfaces, and utensils clean and free of accumulation of dust, dirt, food residue, and other debris.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two hundred fifty dollars **($250.00)**.

68) Order Type and Number: Consent Order 2019-206-07-030
Order Date: July 8, 2019
Individual/Entity: **Sweetfrog**
Facility: Sweetfrog
Location: 604 St. James Avenue, Unit K
Goose Creek, SC 29445
Mailing Address: 10800 Midlothian Turnpike, Suite 300
North Chesterfield, VA 23235
County: Berkeley
Previous Orders: None
Permit Number: 08-206-08978
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Sweetfrog (Individual/Entity) is a restaurant located in Goose Creek, South Carolina. The Department conducted inspections on July 13, 2017, May 9, 2018, and March 22, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that outer openings of the retail food establishment were protected against the entry of insects and rodents by filling or closing the holes and other gaps along floors, walls and ceiling, closed tight-fitting windows and solid, self-closing doors.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two hundred dollars **($200.00)**.

69) Order Type and Number: Consent Order 2019-206-07-049
Order Date: July 8, 2019
Individual/Entity: **Fleet Landing**
Facility: Fleet Landing
Location: 186 Concord Street
Charleston, SC 29401
Mailing Address: P.O. Box 20579
Charleston, SC 29401
County: Charleston
Previous Orders: None
Permit Number: 10-206-05182
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Fleet Landing (Individual/Entity) is a restaurant located in Charleston, South Carolina. The Department conducted inspections on May 17, 2018, May 9, 2019, and May 17, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to properly cool cooked time/temperature control for safety foods and failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

70) Order Type and Number: Consent Order 2019-211-07-002
Order Date: July 8, 2019
Individual/Entity: **Chihuahua Super Market**
Facility: Chihuahua Super Market
Location: 3387 Ashley Phosphate Road
Charleston, SC 29418
Mailing Address: Same
County: Charleston
Previous Orders: 2016-211-07-001 ($1,200.00);
2018-211-07-001 ($800.00)
Permit Number: 10-211-09349
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Chihuahua Super Market (Individual/Entity) is a retail food store located in Charleston, South Carolina. The Department conducted an inspection on February 28, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

71) Order Type and Number: Consent Order 2019-206-06-051
Order Date: July 9, 2019
Individual/Entity: **Ricetown Convenient Store**
Facility: Ricetown Convenient Store
Location: 10144 Carvers Bay Road
Hemingway, SC 29554
Mailing Address: Same
County: Georgetown
Previous Orders: None
Permit Number: 22-206-09218
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Ricetown Convenient Store (Individual/Entity) is a convenience store located in Hemingway, South Carolina. The Department conducted inspections on December 5, 2017, December 14, 2017, February 20, 2018, December 4, 2018, December 19, 2018, January 3, 2019, January 14, 2019, and April 12, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that a person in charge is certified by a food protection manager certification program that is recognized by the Conference for Food Protection; failed to ensure that at least one (1) handwashing sink necessary for their convenient use by employees was provided; failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded; failed to ensure that all equipment installed in a retail food establishment after the effective date of this regulation shall be certified or classified and listed to National Sanitation Foundation (NSF)/American National Standards Institute (ANSI) Commercial Food Equipment Standards, or Baking Industry Sanitation Standards Committee (BISSC) or other accredited ANSI food equipment sanitation certification recognized by the Department; failed to ensure a sink with at least three (3) compartments was provided for manually washing, rinsing, and sanitizing equipment and utensils; and failed to meet the lighting intensity as measured by foot candles throughout specific areas of the facility.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two thousand, two hundred dollars **($2,200.00)**.

72) Order Type and Number: Consent Order 2019-206-01-037
Order Date: July 10, 2019
Individual/Entity: **Chili's Grill & Bar #557**
Facility: Chili's Grill & Bar #557
Location: 3803 Clemson Boulevard
Anderson, SC 29621
Mailing Address: 3000 Olympus Boulevard
Dallas, TX 75019

County: Anderson
Previous Orders: 2018-206-01-020 ($800.00);
2019-206-01-021 ($250.00)
Permit Number: 04-206-03508
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Chili's Grill & Bar #557 (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted an inspection on May 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that after cleaning and sanitizing, equipment and utensils were properly air-dried before contact with food and may not be cloth dried.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two hundred fifty dollars **($250.00)**.

73) Order Type and Number: Consent Order 2019-206-03-051
Order Date: July 10, 2019
Individual/Entity: **Quick Stop #2**
Facility: Quick Stop #2
Location: 9401 Wilson Boulevard
Columbia, SC 29203
Mailing Address: Same
County: Richland
Previous Orders: None
Permit Number: 40-206-07215
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Quick Stop #2 (Individual/Entity) is a convenience store located in Columbia, South Carolina. The Department conducted inspections on July 25, 2018, April 17, 2019, April 26, 2019, May 3, 2019, May 13, 2019, May 20, 2019, May 30, 2019, and June 7, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; failed to provide water at a temperature of at least 100°F through a mixing valve or combination faucet at the handwashing sink(s); failed to provide individual disposable towels at each hand washing sink or group of adjacent handwashing sinks; and failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of five thousand dollars **($5,000.00)**.

74) Order Type and Number: Consent Order 2019-206-03-061
Order Date: July 10, 2019
Individual/Entity: **Higher Ground Char House**
Facility: Higher Ground Char House

Location: 211 Chapin Road
Chapin, SC 29036
Mailing Address: Same
County: Lexington
Previous Orders: None
Permit Number: 32-206-06545
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Higher Ground Char House (Individual/Entity) is a restaurant located in Chapin, South Carolina. The Department conducted inspections on June 26, 2018, October 24, 2018, and May 8, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure employees wash hands after engaging in activities that contaminate their hands.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

75) Order Type and Number: Consent Order 2019-206-03-064
Order Date: July 10, 2019
Individual/Entity: **Cabanas Restaurant**
Facility: Cabanas Restaurant
Location: 825 Sunset Boulevard
West Columbia, SC 29169
Mailing Address: 148 Cherry Grove Drive
West Columbia, SC 29170
County: Lexington
Previous Orders: None
Permit Number: 32-206-06356
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Cabanas Restaurant (Individual/Entity) is a restaurant located in West Columbia, South Carolina. The Department conducted inspections on June 1, 2017, June 2, 2017, June 1, 2018, and May 28, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

76) Order Type and Number: Consent Order 2019-206-03-066
Order Date: July 10, 2019
Individual/Entity: **Panera Bread #4949**
Facility: Panera Bread #4949
Location: 631-6 Promenade Place
Columbia, SC 29229

Mailing Address: 3900 East Market Street
Warren, OH 44481
County: Richland
Previous Orders: None
Permit Number: 40-206-07914
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Panera Bread #4949 (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on January 8, 2019, May 24, 2019, and May 30, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

77) Order Type and Number: Consent Order 2019-206-06-077
Order Date: July 10, 2019
Individual/Entity: **263 Money Saver**
Facility: 263 Money Saver
Location: 263 US Highway 521
Greeleyville, SC 29056
Mailing Address: Same
County: Williamsburg
Previous Orders: None
Permit Number: 45-206-00397
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: 263 Money Saver (Individual/Entity) is a convenience store located in Greeleyville, South Carolina. The Department conducted inspections on March 15, 2018, January 16, 2019, and May 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded and failed to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

78) Order Type and Number: Consent Order 2019-206-07-039
Order Date: July 10, 2019
Individual/Entity: **Margaritas**
Facility: Margaritas
Location: 223 North Main Street

	Summerville, SC 29483
Mailing Address:	Same
County:	Dorchester
Previous Orders:	2015-206-07-039 ($800.00)
Permit Number:	18-206-05824
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Margaritas (Individual/Entity) is a restaurant located in Summerville, South Carolina. The Department conducted inspections on April 10, 2017, April 5, 2018, and April 2, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

79)	Order Type and Number:	Consent Order 2019-206-01-027
	Order Date:	July 12, 2019
	Individual/Entity:	**Domino's Pizza**
	Facility:	Domino's Pizza
	Location:	4420 Highway 24 Anderson, SC 29626
	Mailing Address:	100 Harrison Harbor Way Anderson, SC 29625
	County:	Anderson
	Previous Orders:	2018-206-01-024 ($200.00)
	Permit Number:	04-206-03307
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Domino's Pizza (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted inspections on July 7, 2017, June 6, 2018, and April 26, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that the retail food establishment obtained a variance from the Department before special processes were implemented and failed to ensure that after cleaning and sanitizing, equipment and utensils were properly air-dried before contact with food and may not be cloth dried.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of five hundred dollars **($500.00)**.

80)	Order Type and Number:	Consent Order 2019-206-02-034
	Order Date:	July 12, 2019
	Individual/Entity:	**Cazbah**
	Facility:	Cazbah

Location: 16 West McBee Avenue
Greenville, SC 29601
Mailing Address: Same
County: Greenville
Previous Orders: 2018-206-02-045 ($800.00)
Permit Number: 23-206-07178
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Cazbah (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted an inspection on April 30, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

81) Order Type and Number: Consent Order 2019-206-06-062
Order Date: July 12, 2019
Individual/Entity: **Crab Daddy's Calabash Seafood**
Facility: Crab Daddy's Calabash Seafood
Location: 3043 Highway 17 South
Murrells Inlet, SC 29576
Mailing Address: Same
County: Horry
Previous Orders: None
Permit Number: 26-206-13411
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Crab Daddy's Calabash Seafood (Individual/Entity) is a restaurant located in Murrells Inlet, South Carolina. The Department conducted inspections on May 5, 2017, July 25, 2017, May 8, 2018, and April 24, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods and failed to properly thaw time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

82) Order Type and Number: Consent Order 2019-206-06-066
Order Date: July 12, 2019
Individual/Entity: **NY Style Pizzeria**
Facility: NY Style Pizzeria
Location: 706 North Ocean Boulevard

	Myrtle Beach, SC 29577
Mailing Address:	P.O. Box 3034
	Myrtle Beach, SC 29577
County:	Horry
Previous Orders:	None
Permit Number:	26-206-12078
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: NY Style Pizzeria (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on March 13, 2018, October 18, 2018, October 25, 2018, and April 24, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods and failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

83)	Order Type and Number:	Consent Order 2019-206-06-076
	Order Date:	July 12, 2019
	Individual/Entity:	**River City Cafe**
	Facility:	River City Café
	Location:	208 73rd Avenue North
		Myrtle Beach, SC 29572
	Mailing Address:	2504 South Kings Highway
		Myrtle Beach, SC 29577
	County:	Horry
	Previous Orders:	2016-206-06-040 ($800.00);
		2018-206-06-160 ($1,000.00)
	Permit Number:	26-206-07455
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: River City Café (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted an inspection on May 20, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

84)	Order Type and Number:	Consent Order 2019-206-07-047
	Order Date:	July 12, 2019
	Individual/Entity:	**Burger King #6357**
	Facility:	Burger King #6357

Location: 5125 Ashley Phosphate Road
North Charleston, SC 29418
Mailing Address: P.O. Box 7971
Madison, WI 53713
County: Charleston
Previous Orders: None
Permit Number: 18-206-07600
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Burger King #6357 (Individual/Entity) is a restaurant located in North Charleston, South Carolina. The Department conducted inspections on August 2, 2017, June 26, 2018, April 23, 2019, and May 2, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

85) Order Type and Number: Consent Order 2019-208-04-002
Order Date: July 12, 2019
Individual/Entity: **Bennettsville Middle School**
Facility: Bennettsville Middle School
Location: 701 Cheraw Street
Bennettsville, SC 29512
Mailing Address: P.O. Box 947
Bennettsville, SC 29512
County: Marlboro
Previous Orders: None
Permit Number: 34-208-00040
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Bennettsville Middle School (Individual/Entity) operates a cafeteria located in Bennettsville, South Carolina. The Department conducted inspections on October 16, 2017, April 24, 2018, November 30, 2018, April 8, 2019, and April 12, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to protect food from contamination by storing in a clean, dry location, where it is not exposed to splash, dust, or other contamination, at least 6 inches above the floor.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of six hundred dollars **($600.00)**.

86) Order Type and Number: Consent Order 2019-206-03-048
Order Date: July 15, 2019
Individual/Entity: **East Bay Deli**
Facility: East Bay Deli
Location: 108 Sunset Court
West Columbia, SC 29169
Mailing Address: P.O. Box 40787
North Charleston, SC 29423
County: Lexington
Previous Orders: None
Permit Number: 32-206-06616
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: East Bay Deli (Individual/Entity) is a restaurant located in West Columbia, South Carolina. The Department conducted inspections on May 29, 2018, June 7, 2018, and May 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

87) Order Type and Number: Consent Order 2019-206-03-062
Order Date: July 15, 2019
Individual/Entity: **Goodfellas**
Facility: Goodfellas
Location: 760 Highway 378 West, Unit I
Lexington, SC 29072
Mailing Address: 1512 Beulah Road
Leesville, SC 29070
County: Lexington
Previous Orders: 2019-206-03-062 ($1,000.00)
Permit Number: 32-206-06320
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Goodfellas (Individual/Entity) is a restaurant located in Lexington, South Carolina. The Department conducted inspections on April 5, 2018, May 29, 2018, June 7, 2018, and May 20, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods and failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, five hundred dollars **($1,500.00)**.

88) Order Type and Number: Consent Order 2019-206-06-070
Order Date: July 15, 2019
Individual/Entity: **Arby's #6912**
Facility: Arby's #6912
Location: 2709 Dick Pond Road
Myrtle Beach, SC 29575
Mailing Address: 730 Main Street #306
North Myrtle Beach, SC 29582
County: Horry
Previous Orders: 2018-206-06-158 ($200.00)
Permit Number: 26-206-08587
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Arby's #6912 (Individual/Entity) is a restaurant located in Myrtle Beach, South Carolina. The Department conducted inspections on April 4, 2019, April 15, 2019, and April 25, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of five hundred dollars **($500.00)**.

89) Order Type and Number: Consent Order 2019-206-07-027
Order Date: July 15, 2019
Individual/Entity: **Charleston's Chill N Grill**
Facility: Charleston's Chill N Grill
Location: 2810 Ashley Phosphate Road
North Charleston, SC 29418
Mailing Address: Same
County: Charleston
Previous Orders: None
Permit Number: 10-206-09087
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Charleston's Chill N Grill (Individual/Entity) is a restaurant located in North Charleston, South Carolina. The Department conducted inspections on April 17, 2018, June 22, 2018, and March 18, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

90) Order Type and Number: Consent Order 2019-206-07-042
Order Date: July 15, 2019
Individual/Entity: **Clean Eatz of Mt. Pleasant**
Facility: Clean Eatz of Mt. Pleasant
Location: 1455 Stuart Engals Boulevard
Mount Pleasant, SC 29464
Mailing Address: 1304 Professional Drive, Suite E
Myrtle Beach, SC 29577
County: Charleston
Previous Orders: None
Permit Number: 10-206-10554
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Clean Eatz of Mt. Pleasant (Individual/Entity) is a restaurant located in Mount Pleasant, South Carolina. The Department conducted inspections on April 19, 2018, April 9, 2019, April 17, 2019, and April 24, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, three hundred fifty dollars **($1,350.00)**.

91) Order Type and Number: Consent Order 2019-206-01-026
Order Date: July 17, 2019
Individual/Entity: **Long John Silvers**
Facility: Long John Silvers
Location: 3314 A North Main Street
Anderson, SC 29621
Mailing Address: 103 Cooper Street
Babylon, NY 11702
County: Anderson
Previous Orders: None
Permit Number: 04-206-04441
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Long John Silvers (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted inspections on February 12, 2018, January 29, 2019, February 8, 2019, February 13, 2019, February 15, 2019, and February 28, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements and failed to ensure the plumbing system is repaired according to law and maintained in good repair.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

92) Order Type and Number: Consent Order 2019-206-01-034
Order Date: July 17, 2019
Individual/Entity: **Waffle House #1951**
Facility: Waffle House #1951
Location: 1010 Highway 28 Bypass
Anderson, SC 29624
Mailing Address: P.O. Box 6450
Norcross, GA 30091
County: Anderson
Previous Orders: 2018-206-01-034 ($800.00)
Permit Number: 04-206-04000
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Waffle House #1951 (Individual/Entity) is a restaurant located in Anderson, South Carolina. The Department conducted an inspection on May 21, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

93) Order Type and Number: Consent Order 2019-206-03-056
Order Date: July 17, 2019
Individual/Entity: **Ristorante Divino**
Facility: Ristorante Divino
Location: 803 Gervais Street
Columbia, SC 29201
Mailing Address: Same
County: Richland
Previous Orders: None
Permit Number: 40-206-07331
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Ristorante Divino (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on May 18, 2017, May 17, 2018, May 25, 2018, and May 16, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain the proper sanitization concentration in a chemical sanitizer used in a manual or mechanical operation during contact times.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

94) Order Type and Number: Consent Order 2019-206-03-059
Order Date: July 17, 2019
Individual/Entity: **McAlister's Deli #1061**
Facility: McAlister's Deli #1061
Location: 10254 Two Notch Road
Columbia, SC 29229
Mailing Address: P.O. Box 826
Van Wert, OH 45891
County: Richland
Previous Orders: None
Permit Number: 40-206-07762
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: McAlister's Deli #1061 (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on June 22, 2018, July 2, 2018, and May 29, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

95) Order Type and Number: Consent Order 2019-206-03-060
Order Date: July 17, 2019
Individual/Entity: **Waffle House #446**
Facility: Waffle House #446
Location: 2846 Charleston Highway
West Columbia, SC 29169
Mailing Address: P.O. Box 6450
Norcross, GA 30091
County: Lexington
Previous Orders: 2017-206-03-084 ($800.00);
2018-206-03-064 ($1,000.00)
Permit Number: 32-206-00102
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Waffle House #446 (Individual/Entity) is a restaurant located in West Columbia, South Carolina. The Department conducted inspections on May 21, 2018, May 20, 2019, and May 28, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods and failed to ensure that the temperature of the fresh hot water sanitizing rinse as it enters the manifold, may not be more than 194 degrees in a mechanical operation, or less than 165 degrees for a stationary rack, single temperature machine or less than 180 degrees for all other machines.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two thousand dollars **($2,000.00)**.

96) Order Type and Number: Consent Order 2019-206-03-075
Order Date: July 17, 2019
Individual/Entity: **China Garden**
Facility: China Garden
Location: 7120 Parklane Road
Columbia, SC 29223
Mailing Address: Same
County: Richland
Previous Orders: 2014-206-03-108 ($750.00);
2017-206-03-089 ($800.00);
2019-206-03-045 ($1,000.00)
Permit Number: 40-206-06318
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: China Garden (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on October 30, 2018, May 6, 2019, June 27, 2019, and July 5, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two thousand dollars **($2,000.00)**.

97) Order Type and Number: Consent Order 2019-206-06-081
Order Date: July 17, 2019
Individual/Entity: **Buzz's Roost**
Facility: Buzz's Roost
Location: 917 Front Street, Unit B
Georgetown, SC 29440
Mailing Address: Same
County: Georgetown
Previous Orders: None
Permit Number: 22-206-06419
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Buzz's Roost (Individual/Entity) is a restaurant located in Georgetown, South Carolina. The Department conducted inspections on June 19, 2018, August 8, 2018, and May 7, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two hundred dollars **($200.00)**.

98) Order Type and Number: Consent Order 2019-206-04-020
Order Date: July 18, 2019
Individual/Entity: **Corner Connection**
Facility: Corner Connection
Location: 101 Society Hill Road
Darlington, SC 29532
Mailing Address: 119 North Spain Road
Darlington, SC 29532
County: Darlington
Previous Orders: 2019-206-04-005 ($400.00)
Permit Number: 16-206-01943
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Corner Connection (Individual/Entity) is a convenience store located in Darlington, South Carolina. The Department conducted inspections on April 16, 2019, and April 24, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to keep food contact surfaces, nonfood contact surfaces, and utensils clean and free of accumulation of dust, dirt, food residue, and other debris and failed to clean the physical facilities as often as necessary to keep them clean.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of five hundred dollars **($500.00)**.

99) Order Type and Number: Consent Order 2019-206-02-025
Order Date: July 19, 2019
Individual/Entity: **Palmetto Smokehouse & Oyster Bar**
Facility: Palmetto Smokehouse & Oyster Bar
Location: 199 Old Greenville Highway
Clemson, SC 29631
Mailing Address: P.O. Box 188
Pendleton, SC 29670
County: Pickens
Previous Orders: 2018-206-02-027 ($800.00)
Permit Number: 39-206-01771
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Palmetto Smokehouse & Oyster Bar (Individual/Entity) is a restaurant located in Clemson, South Carolina. The Department conducted inspections on March 31, 2017, March 22, 2018, and March 20, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

100) Order Type and Number: Consent Order 2019-206-02-028
Order Date: July 19, 2019
Individual/Entity: **Cantinflas Mexican Restaurant**
Facility: Cantinflas Mexican Restaurant
Location: 10 South Main Street
Greenville, SC 29601
Mailing Address: Same
County: Greenville
Previous Orders: 2016-206-02-030 ($400.00);
2018-206-02-047 ($1,000.00)
Permit Number: 23-206-07370
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Cantinflas Mexican Restaurant (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on April 4, 2019, April 5, 2019, and April 12, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two thousand, seven hundred fifty dollars **($2,750.00)**.

101) Order Type and Number: Consent Order 2019-206-02-037
Order Date: July 19, 2019
Individual/Entity: **McDonald's**
Facility: McDonald's
Location: 5050 Old Buncombe Road
Greenville, SC 29640
Mailing Address: 1304 East Main Street, Suite B
Greenville, SC 29617
County: Greenville
Previous Orders: None
Permit Number: 23-206-03923
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: McDonald's (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on January 10, 2017, December 14, 2017, and November 26, 2018. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

102) Order Type and Number: Consent Order 2019-206-02-040
Order Date: July 19, 2019
Individual/Entity: **Todaro Pizza**
Facility: Todaro Pizza
Location: 105 Sloan Street
Clemson, SC 29631
Mailing Address: Same
County: Pickens
Previous Orders: None
Permit Number: 39-206-01114
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Todaro Pizza (Individual/Entity) is a restaurant located in Clemson, South Carolina. The Department conducted inspections on September 26, 2017, July 16, 2018, and May 20, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure written procedures were in place and made available to the Department when the facility uses time as a public health control.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

103) Order Type and Number: Consent Order 2019-208-04-001
Order Date: July 19, 2019
Individual/Entity: **Marion High School Lunchroom**
Facility: Marion High School Lunchroom
Location: 1205 South Main Street
Marion, SC 29571
Mailing Address: Same
County: Marion
Previous Orders: None
Permit Number: 33-208-00105
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Marion High School Lunchroom (Individual/Entity) operates a cafeteria located in Marion, South Carolina. The Department conducted inspections on January 18, 2018, November 2, 2018, and April 29, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

104) Order Type and Number: Consent Order 2019-206-01-029
Order Date: July 23, 2019
Individual/Entity: **Fatz**
Facility: Fatz
Location: 1302 Montague Avenue Extension
Greenwood, SC 29649
Mailing Address: 4325 Wade Hampton Boulevard, Suite B
Taylors, SC 29687
County: Greenwood
Previous Orders: None
Permit Number: 24-206-03159
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Fatz (Individual/Entity) is a restaurant located in Greenwood, South Carolina. The Department conducted inspections on April 17, 2019, April 25, 2019, and May 3, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of eight hundred dollars **($800.00)**.

105) Order Type and Number: Consent Order 2019-206-02-044
Order Date: July 23, 2019
Individual/Entity: **Pretzel Maker**
Facility: Pretzel Maker
Location: 700 Haywood Road, Suite 2103
Greenville, SC 29607
Mailing Address: Same
County: Greenville
Previous Orders: None
Permit Number: 23-206-11569
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Pretzel Maker (Individual/Entity) is a restaurant located in Greenville, South Carolina. The Department conducted inspections on January 22, 2019, March 21, 2019, May 21, 2019, and May 29, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to ensure that when time without temperature control is used as a public health control, the food in unmarked containers or packages shall be discarded and failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, six hundred dollars **($1,600.00)**.

106)	Order Type and Number:	Consent Order 2019-206-03-046
	Order Date:	July 23, 2019
	Individual/Entity:	**KJ's IGA Market Deli/Bakery**
	Facility:	KJ's IGA Market Deli/Bakery
	Location:	217 West Columbia Avenue Batesburg, SC 29006
	Mailing Address:	P.O. Box 1629 Lake City, SC 29560
	County:	Lexington
	Previous Orders:	2016-206-03-028 ($800.00); 2016-206-03-017 ($2,400.00); 2018-206-03-143 ($600.00)
	Permit Number:	32-206-06279
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: KJ's IGA Market Deli/Bakery (Individual/Entity) operates a deli/bakery located in Batesburg, South Carolina. The Department conducted inspections on January 26, 2018, August 27, 2018, and April 29, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods; failed to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues; failed to clean the physical facilities as often as necessary to keep them clean; and failed to maintain the premises free of insects, rodents, and other pests.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand, two hundred fifty dollars **($1,250.00)**.

107)	Order Type and Number:	Consent Order 2019-206-03-050
	Order Date:	July 23, 2019
	Individual/Entity:	**Substation II**
	Facility:	Substation II
	Location:	736 Saint Andrews Road, Suite G Columbia, SC 29210
	Mailing Address:	Same
	County:	Lexington
	Previous Orders:	2018-206-03-042 ($200.00)
	Permit Number:	32-206-06310
	Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Substation II (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on May 19, 2017, April 17, 2018, April 15, 2019, April 22, 2019, and May 2, 2019. The Individual/Entity has violated the South Carolina Retail Food

Establishment Regulation as follows: failed to ensure that equipment is maintained in a state of repair and condition that meets the regulation requirements; failed to ensure that multiuse food-contact surfaces were smooth; free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections, free of sharp internal angles, corners, and crevices, finished to have smooth welds and joints, and accessible for cleaning; failed to ensure a sink with at least three (3) compartments was provided for manually washing, rinsing, and sanitizing equipment and utensils; and failed to keep equipment food contact surfaces and utensils clean to sight and touch.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two thousand, five hundred dollars **($2,500.00)**.

108) Order Type and Number: Consent Order 2019-206-03-074
Order Date: July 23, 2019
Individual/Entity: **North Main Fish Market**
Facility: North Main Fish Market
Location: 6010 North Main Street
Columbia, SC 29203
Mailing Address: Same
County: Richland
Previous Orders: None
Permit Number: 40-206-07980
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: North Main Fish Market (Individual/Entity) is a restaurant located in Columbia, South Carolina. The Department conducted inspections on January 2, 2019, June 13, 2019, and June 19, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to clean non-food contact surfaces at a frequency to preclude accumulation of soil residues.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two hundred dollars **($200.00)**.

109) Order Type and Number: Consent Order 2019-206-06-072
Order Date: July 23, 2019
Individual/Entity: **Clubhouse Pub & Grub**
Facility: Clubhouse Pub & Grub
Location: 10225 Ocean Highway
Pawleys Island, SC 29585
Mailing Address: 1612 Running Water Road
Murrells Inlet, SC 29576
County: Georgetown
Previous Orders: 2017-206-06-070 ($740.00)
Permit Number: 22-206-06106
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Clubhouse Pub & Grub (Individual/Entity) is a restaurant located in Pawleys Island, South Carolina. The Department conducted inspections on September 5, 2018, and May 13, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of two thousand dollars **($2,000.00)**.

110)

Order Type and Number:	Consent Order 2019-206-06-073
Order Date:	July 23, 2019
Individual/Entity:	**Carver's Bay Convenience Store**
Facility:	Carver's Bay Convenience Store
Location:	13017 Choppee Road Hemingway, SC 29440
Mailing Address:	Same
County:	Georgetown
Previous Orders:	2018-206-06-059 ($400.00); 2018-206-06-165 ($400.00)
Permit Number:	22-206-06242
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Carver's Bay Convenience Store (Individual/Entity) is a convenience store located in Hemingway, South Carolina. The Department conducted inspections on May 31, 2018, December 11, 2018, and April 29, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to store poisonous or toxic materials so that they cannot contaminate food equipment, utensils, linens, and single-service and single-use articles.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

111)

Order Type and Number:	Consent Order 2019-206-06-074
Order Date:	July 23, 2019
Individual/Entity:	**Webster's Low Country Grill**
Facility:	Webster's Low Country Grill
Location:	14276 Ocean Highway Pawleys Island, SC 29585
Mailing Address:	Same
County:	Georgetown
Previous Orders:	2017-206-06-055 ($800.00)
Permit Number:	22-206-05228
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Webster's Low Country Grill (Individual/Entity) is a restaurant located in Hemingway, South Carolina. The Department conducted inspections on October 11, 2017, June 21, 2018, and May 14, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of three thousand dollars **($3,000.00)**.

112) Order Type and Number: Consent Order 2019-206-06-087
Order Date: July 23, 2019
Individual/Entity: **Piggly Wiggly #80 Deli**
Facility: Piggle Wiggly #80 Deli
Location: 15 West Ashland Street
Andrews, SC 29510
Mailing Address: 415 North Salme Avenue
Sumter, SC 29150
County: Georgetown
Previous Orders: 2019-206-06-036 ($800.00)
Permit Number: 22-206-06238
Violations Cited: S.C. Code Ann. Regs. 61-25

Summary: Piggly Wiggly #80 Deli (Individual/Entity) operates a deli located in Andrews, South Carolina. The Department conducted inspections on August 15, 2018, February 11, 2019, and May 13, 2019. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: failed to maintain proper hot and cold holding temperatures of time/temperature control for safety foods.

Action: The Individual/Entity is required to: operate and maintain the facility in accordance with the requirements of all applicable regulations, including S.C. Regs. 61-25, and pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Onsite Wastewater Enforcement

113) Order Type and Number: Administrative Order 19-33-OSWW
Order Date: July 17, 2019
Individual/Entity: **Irene Marquis**
Facility: Irene Marquis
Location: 629 Stonehaven Court
Clover, SC 29710
Mailing Address: Same
County: York
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Irene Marquis (Individual/Entity) owns property located in Clover, South Carolina. The Department conducted an investigation on May 23, 2019, and observed domestic wastewater discharging onto the surface of the ground and running off the property onto an adjacent property. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system; or ensure the residence remains vacated until adequate repairs are made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

114)

Order Type and Number:	Administrative Order 19-35-OSWW
Order Date:	July 17, 2019
Individual/Entity:	**Olin Gilstrap** **Marie Moreno**
Facility:	Olin Gilstrap Marie Moreno
Location:	306 Chesapeake Trail Pickens, SC 29671
Mailing Address:	Same
County:	Spartanburg
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Olin Gilstrap and Marie Moreno (Individuals/Entities) own property located in Pickens, South Carolina. The Department conducted an investigation on June 11, 2019, and observed domestic wastewater discharging onto the surface of the ground and running off the property into a creek found in the back of the property. The Individuals/Entities have violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system; or ensure the residence remains vacated until adequate repairs are made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

115) Order Type and Number: Consent Order 19-14-OSWW
Order Date: July 2, 2019
Individual/Entity: **Samuel Bethea, Individually and d.b.a. Bethea Septic Tank**
Facility: Samuel Bethea
Location: Highway 79 West
Bennettsville, SC 29512
Mailing Address: 1028 Betheas Way
Bennettsville, SC 29512
County: Marlboro
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Samuel Bethea, Individually and d.b.a. Bethea Septic Tank (Individual/Entity), holds a Department-issued license to engage in installing and repairing of onsite wastewater systems. The Department conducted an investigation on March 29, 2019, at Hwy 79 W, Bennettsville, South Carolina 29512, and observed that a 1000-gallon septic tank had been installed. The Individual/Entity has violated the South Carolina Onsite Wastewater Systems (OSWW) Regulation as follows: failed to ensure that all systems for which the licensee is responsible are constructed, repaired, and cleaned in accordance with Regulation 61-56 and other applicable regulations, permits, and standards issued by the Department.

Action: The Individual/Entity is required to: henceforth obtain a proper permit prior to construction of any OSWW system; ensure use of approved aggregate in any OSWW systems installed or repaired; ensure that the unpermitted OSWW system installed at the Site is properly removed; and pay a civil penalty in the amount of one thousand dollars **($1,000.00).**

116) Order Type and Number: Consent Order 19-17-OSWW
Order Date: July 2, 2019
Individual/Entity: **Faith Hazelwood**
Facility: Faith Hazelwood
Location: 228 Breezy Bay Circle
Gilbert, SC 29054
Mailing Address: 228 Breezy Bay Circle
Gilbert, SC 29054
County: Lexington
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Faith Hazelwood (Individual/Entity) owns property located in Lexington, South Carolina. The Department conducted an investigation on August 23, 2018, and observed domestic wastewater discharging onto the surface of the ground and running off the property onto an adjacent property. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit

from the Department and occupied a dwelling for more than two hours per day without an approved method for the treatment and disposal of domestic wastewater.

Action: The Individual/Entity is required to: connect all residences at the Site to the public sewer; contact the Department with confirmation from the Town of Lexington that the Site is connected to the public sewer system; or immediately vacate all residences at the Site; ensure the residences remain vacated until the Department has confirmed that the Site is connected to public sewer; and pay a **suspended penalty** in the amount of seven thousand, five hundred dollars **($7,500.00)** should any requirement of the Order not be met.

117)	Order Type and Number:	Consent Order 19-18-OSWW
	Order Date:	July 2, 2019
	Individual/Entity:	**Deborah Hayes**
	Facility:	Deborah Hayes
	Location:	261 Giles Road McConnells, SC
	Mailing Address:	583 North Burris Road Sharon, SC 29742
	County:	York
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Deborah Hayes (Individual/Entity) owns property located in McConnells, South Carolina. The Department conducted an investigation on January 3, 2019, and observed domestic wastewater discharging onto the surface of the ground and running off the property onto an adjacent property. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system; ensure the residence remains vacated until adequate repairs are made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

118)	Order Type and Number:	Consent Order 19-21-OSWW
	Order Date:	July 2, 2019
	Individual/Entity:	**John William Roper**
	Facility:	John William Roper
	Location:	5 Stevens Court Inman, SC
	Mailing Address:	296 Jersey Road

	Inman, SC 29349
County:	Spartanburg
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: John William Roper (Individual/Entity) owns property located in Inman, South Carolina. The Department conducted an investigation on April 11, 2019, and observed domestic wastewater discharging onto the surface of the ground and running off the property onto an adjacent property. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system; ensure the residence remains vacated until adequate repairs are made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

119)	Order Type and Number:	Consent Order 19-23-OSWW
	Order Date:	July 2, 2019
	Individual/Entity:	**Joseph Vaughan** **Angela Vaughan**
	Facility:	Joseph Vaughan Angela Vaughan
	Location:	313 Beaver Dam Road Chesnee, SC 29323
	Mailing Address:	Same
	County:	Spartanburg
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Joseph and Angela Vaughan (Individuals/Entities) own property located in Chesnee, South Carolina. The Department conducted an investigation on February 20, 2019, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity have violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system; ensure the residence remains vacated until adequate repairs are

made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

120)	Order Type and Number:	Consent Order 19-28-OSWW
	Order Date:	July 8, 2019
	Individual/Entity:	**David Ledford** **Todd Ledford**
	Facility:	David Ledford Todd Ledford
	Location:	545 South Old Piedmont Highway Greenville, SC
	Mailing Address:	211 South Calhoun Street Greenville, SC 29601
	County:	Greenville
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: David Ledford and Todd Ledford (Individuals/Entities) own property located in Greenville, South Carolina. The Department conducted an investigation on April 16, 2019, and observed domestic wastewater discharging onto the surface of the ground. The Individuals/Entities have violated the South Carolina Onsite Wastewater Systems (OSWW) Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system; ensure the residence remains vacated until adequate repairs are made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

121)	Order Type and Number:	Consent Order 19-29-OSWW
	Order Date:	July 8, 2019
	Individual/Entity:	**Tammy Barber**
	Facility:	Tammy Barber
	Location:	19 Melodyaire Court Travelers Rest, SC 29690
	Mailing Address:	Same
	County:	Greenville
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Tammy Barber (Individual/Entity) owns property located at in Travelers Rest, South Carolina. The Department conducted an investigation on April 16, 2019, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system; ensure the residence remains vacated until adequate repairs are made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

122)	Order Type and Number:	Consent Order 19-20-OSWW
	Order Date:	July 9, 2019
	Individual/Entity:	**Andy Burns**
	Facility:	Andy Burns
	Location:	360 Sunset Road Landrum, SC 29356
	Mailing Address:	829 Cumberland Drive Greer, SC 29651
	County:	Spartanburg
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56 and 61-56.2

Summary: Andy Burns, doing business as BSI, LLC, (Individual/Entity) holds a Department-issued license to engage in installing and repairing of onsite wastewater systems. The Department received information on May 2, 2019, that an onsite wastewater (OSWW) system had been installed without proper permitting from the Department. The Individual/Entity has violated the South Carolina Onsite Wastewater Systems Regulation as follows: failed to construct, upgrade, expand, or operate an onsite wastewater system with a permit issued by the Department for the specific construction and operation proposed.

Action: The Individual/Entity is required to: henceforth obtain a proper permit prior to construction of any OSWW systems; ensure that the unpermitted OSWW system installed at the Site is properly removed; and pay a civil penalty in the amount of one thousand dollars **($1,000.00).**

123)	Order Type and Number:	Consent Order 19-22-OSWW
	Order Date:	July 9, 2019
	Individual/Entity:	**Clifford Allen** **Deborah Allen**
	Facility:	Clifford Allen Deborah Allen

Location:	2017 West Springs Highway, Lot 1 Jonesville, SC 29353
Mailing Address:	Same
County:	Union
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Clifford Allen and Deborah Allen (Individuals/Entities) own property located in Jonesville, South Carolina. The Department conducted an investigation on January 2, 2019, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic wastewater to the OSWW system; ensure the residence remains vacated until adequate repairs are made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

124)

Order Type and Number:	Consent Order 19-31-OSWW
Order Date:	July 15, 2019
Individual/Entity:	**Annie Maud Foster (deceased)** **Edna Stevenson (daughter/occupant)**
Facility:	Annie Maud Foster (deceased) Edna Stevenson (daughter/occupant)
Location:	124 Hilly Hill Road Duncan, SC 29334
Mailing Address:	Same
County:	Spartanburg
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Annie Maud Foster (Individual/Entity) owns property located in Duncan, South Carolina. The Department conducted an investigation on May 9, 2019, and observed domestic wastewater discharging onto the surface of the ground. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to ensure that no septic tank effluent, domestic wastewater, or sewage was discharged to the surface of the ground without an appropriate permit from the Department.

Action: The Individual/Entity is required to: repair the OSWW system within five (5) days to effectively stop the discharging of septic tank effluent or domestic wastewater or sewage to the surface of the ground; or immediately vacate the residence to eliminate the flow of domestic

wastewater to the OSWW system; ensure the residence remains vacated until adequate repairs are made to the OSWW system to eliminate the discharges of septic tank effluent or domestic wastewater or sewage to the surface of the ground; and pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

[*] Unless otherwise specified, "Previous Orders" as listed in this report include orders issued by Environmental Affairs Programs within the last five (5) years.

(x) ACTION/DECISION
( ) INFORMATION

Date: September 12, 2019

To: S.C. Board of Health and Environmental Control

From: Office of Ocean and Coastal Resource Management

Re: Notice of Proposed Regulation Amending R.30-1, *Statement of Policy*, and R.30-14, *Administrative Procedures*.

I. Introduction

The Office of Ocean and Coastal Resource Management proposes the attached Notice of Proposed Regulation amending R.30-1, *Statement of Policy*, and R.30-14, *Administrative Procedures*, for publication in the September 27, 2019, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 48-39-10 *et seq.*, which require the Department of Health and Environmental Control ("Department") to establish and review the position of the state's beachfront jurisdictional baselines and setback lines every seven (7) to ten (10) years. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. The Office of Ocean and Coastal Resource Management proposes amending R.30-1.D.(43) and R.30-14.E., F., and G. to incorporate state statutory changes. The Beachfront Management Reform Act, Act 173 of 2018 ("Act"), requires the Department to establish, based on best available data, the position of baselines and setback lines during establishment cycles not less than every seven (7) years and not more than every ten (10) years following a previous establishment cycle. The purpose of these jurisdictional lines is to delineate the extent of the Department's direct permitting authority for activities within defined beaches and beach/dune system critical areas.

2. The Act establishes the position of the jurisdictional baselines and setback lines for the 2018 establishment cycle. Section 8 of the Act requires the Department to promulgate regulations for implementation, including provisions to locate a primary oceanfront sand dune.

3. The Office of Ocean and Coastal Resource Management convened a Beachfront Jurisdictional Line Stakeholder Workgroup ("Workgroup") in 2018 to provide input for this process. The Workgroup was composed of thirteen (13) members representing local governments, community associations, the real estate community, academic institutions, private-sector consultants, and non-profit organizations. The Workgroup was charged with providing recommendations to the Department for implementing future jurisdictional line review processes. The proposed amendments are based on final recommendations of the Workgroup and associated public input.

4. The Department had a Notice of Drafting published in the April 26, 2019, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments during the Notice of Drafting comment period.

5. The Office of Ocean and Coastal Resource Management conducted three (3) informational forums to provide the public with the opportunity to discuss the process and outcomes of the Beachfront Jurisdictional Line Stakeholder Workgroup. These forums took place in Myrtle Beach, Charleston, and Hardeeville/Bluffton on July 10, 11, and 18, 2019, respectively.

6. Appropriate Department staff conducted an internal review of the proposed amendments from August 15-20, 2019.

III. Request for Approval

The Office of Ocean and Coastal Resource Management respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 27, 2019, *State Register*.

Elizabeth B. von Kolnitz
Bureau Chief, OCRM

Myra C. Reece
Director, Environment Affairs

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the April 26, 2019, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.30-1, *Statement of Policy*, and 30-14, *Administrative Procedures*

September 12, 2019

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 30
Statutory Authority: 1976 Code Sections 48-39-10 et. seq.

30-1. Statement of Policy.
30-14. Administrative Procedures.

Preamble:

The Department of Health and Environmental Control ("Department") proposes amending R.30-1.D(43) and R.30-14.E., F., and G. to incorporate state statutory changes. The Beachfront Management Reform Act, Act 173 of 2018 ("Act"), requires the Department to establish, based on best available data, the position of baselines and setback lines during establishment cycles not less than every seven (7) years and not more than every ten (10) years following a previous establishment cycle. The purpose of these jurisdictional lines is to delineate the extent of the Department's direct permitting authority for activities within the defined beaches and beach/dune system critical areas.

The Act establishes the position of the jurisdictional baselines and setback lines for the 2018 establishment cycle. Section 8 of the Act requires the Department to promulgate regulations for implementation, including provisions to locate a primary oceanfront sand dune. The Department convened a Beachfront Jurisdictional Line Stakeholder Workgroup in 2018 to provide input into this process.

The proposed amendments are based on final recommendations of the workgroup and associated public engagement and input. The proposed amendments provide clarity and standards to be utilized in the establishment of the state's beachfront jurisdictional lines. The proposed amendments also modify specific procedures related to appeals and movement of the jurisdictional lines to comply with Act 173 and Coastal Zone Critical Areas, Act 197 of 2016.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

The Department had a Notice of Drafting published in the April 26, 2019, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments

R.30-1.D(43) Amend definition to clarify the characteristics associated with a primary oceanfront sand dune used to establish the beachfront jurisdictional baseline.

R.30-14.E Amend title to conform with language in statutory procedures and to delete statutory citation.

R.30-14.E(1) Amend to include the statutory timeframes for establishment cycles for state beachfront jurisdictional baselines and setback lines pursuant to S.C. Code Section 48-39-280.

R.30-14.E(2) Amend to include the statutory notification process for establishing beachfront jurisdictional baselines and setback lines to comply with Act 173 of 2018.

R.30-14.E(3) Add subsection to allow a process for revising establishment dates for a specific geographical location if certain qualifications associated with a beach renourishment project are met.

R.30-14.E(4) Add subsection to clarify that establishment of beachfront jurisdictional baselines and setback lines must be completed within statutory timeframes if construction of the qualifying beach renourishment project has not started within one year.

R.30-14.F Delete to comply with Act 173 of 2018.

R.30-14.G Delete to comply with Act 197 of 2016 and reserve.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments to Liz Hartje of the Office of Ocean and Coastal Resource Management, S.C. Department of Health and Environmental Control, 1362 McMillan Avenue, Suite 400, Charleston, SC 29405; hartjeen@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 28, 2019, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments during its December 12, 2019, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agency/docs/AGENDA.PDF.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/.

Preliminary Fiscal Impact Statement

The Department estimates no additional cost incurred by the state or its political subdivisions as a result of the promulgation, approval, and implementation of this amendment. The Department will use existing staff and resources to implement these proposed amendments.

Statement of Need and Reasonableness

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 30-1, Statement of Policy, and 30-14, Administrative Procedures.

Purpose: The Department proposes amending R.30-1.D.(43) and R.30-14.E., F., and G. to incorporate state statutory changes. The Beachfront Management Reform Act, Act 173 of 2018 ("Act"), requires the Department to establish, based on best available data, the position of baselines and setback lines during

establishment cycles not less than every seven (7) years and not more than every ten (10) years following a previous establishment cycle. The purpose of these jurisdictional lines is to delineate the extent of the Department's direct permitting authority for activities within the defined beaches and beach/dune system critical areas. Section 8 of the Act requires the Department to promulgate regulations for implementation, including provisions to locate a primary oceanfront sand dune. The proposed amendments provide clarity and standards to be utilized in the establishment of the state's beachfront jurisdictional lines. The proposed amendments also modify specific procedures related to appeals and movement of the jurisdictional lines to comply with Act 173 and Coastal Zone Critical Areas, Act 197 of 2016.

Legal Authority: 1976 Code Sections 48-39-10 et. seq.

Plan for Implementation: The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to these proposed amendments. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendments and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department proposes amending R.30-1.D.(43) and R.30-14.E., F., and G. to incorporate state statutory changes. The Department convened a Beachfront Jurisdictional Line Stakeholder Workgroup in 2018 to provide input into this process. The proposed amendments are based on final recommendations of the workgroup and associated public engagement and input. The proposed amendments modify specific procedures related to appeals and movement of the jurisdictional lines to comply with Act 173 and Coastal Zone Critical Areas, Act 197 of 2016.

The proposed amendments are reasonable and necessary to manage the long-term health and sustainability of the state's beaches and beach/dune systems while providing sufficient public input into Department decisions. The proposed amendments also clarify existing regulations to better enable Department staff to more effectively implement the stated policies of the Act.

DETERMINATION OF COSTS AND BENEFITS:

The Department does not anticipate additional cost to the state resulting from administration of these proposed amendments. Benefits to the state include improved management of coastal resources through increased clarity of the regulations. The Department does not anticipate additional cost to the regulated community as a result of these proposed amendments.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Implementation of these proposed amendments seeks to benefit the environment by providing more clarity to the Department's Coastal Division statutory directives to manage the state's beaches and beach/dune critical areas for its citizens. These proposed amendments refine the Department's processes for establishing the state's direct regulatory jurisdiction along the beach and within the beach/dune system. The proposed amendments also provide more clarity to those seeking to utilize these resources.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment and/or public health if these proposed amendments are not implemented. Implementation of these amendments as proposed seeks to benefit the environment by providing more clarity to the Department's Coastal Division statutory directives to manage the state's beaches and beach/dune critical areas for its citizens.

Statement of Rationale:

The Department proposes amending R.30-1.D.(43) and R.30-14.E., F., and G. to incorporate state statutory changes. The Beachfront Management Reform Act, Act 173 of 2018 ("Act"), requires the Department to establish, based on best available data, the position of baselines and setback lines during establishment cycles not less than every seven (7) years and not more than every ten (10) years following a previous establishment cycle. Section 8 of the Act requires the Department to promulgate regulations for implementation, including provisions to locate a primary oceanfront sand dune. The proposed amendments provide clarity and standards to be utilized in the establishment of the state's beachfront jurisdictional lines. The proposed amendments also modify specific procedures related to appeals and movement of the jurisdictional lines to comply with Act 173 and Coastal Zone Critical Areas, Act 197 of 2016.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

30-1. Statement of Policy
30-14. Administrative Procedures.

Statutory Authority: S.C. Code Sections 48-39-10 et. seq

Revise 30-1.D(43), definition of "Primary Oceanfront Sand Dunes" to read:

(43) Primary Oceanfront Sand Dunes - those dunes ~~which~~ that constitute the front row of dunes adjacent to the Atlantic Ocean.~~, are partially or wholly seaward of the setback line, are not landward of an existing functional erosional control device, and~~ For the purposes of establishing the jurisdictional baseline, the dune must have a minimum height of thirty-six (36) inches, as measured vertically from the ~~crest to the~~ seaward toe to the crest of the dune.~~ For purposes of establishing the baseline, this dune must also~~ The dune must also form a nearly continuous ~~line~~ dune ridge for 500 shore parallel feet and may exhibit minimal breaks such as those resulting from pedestrian or emergency vehicle access points. This dune typically exhibits the presence of stable, native vegetation, and is not scarped, eroded, or overtopped by the highest predicted astronomical tides. However, this dune may be inundated by storm surge which normally accompanies major coastal storm events.

Revise R.30-14.E to read:

E. Procedures for Adopting Baselines and ~~Erosion Rates (Section 48-39-280)~~ Setback Lines.

~~(1) Following the establishment of the interim baselines, erosion rates, and setback lines pursuant to Section 48-39-280(C) and any amendments or revisions thereto, the Department will adopt final baselines, erosion rates, and setback lines as part of the state comprehensive beach management plan pursuant to~~

~~Section 48-39-320. The following procedure will be used for the establishment of final baselines, erosion rates, and setback lines:~~

~~(a) The proposed baseline, erosion rate, and setback line for a region, island or part thereof, or other geographic area of South Carolina's ocean shoreline shall be made available to the public for inspection at each of the Department's offices;~~

~~(b) the Department shall afford the public a thirty-day comment period;~~

~~(c) the Department shall afford the opportunity for a public hearing.~~

~~(2) The Department shall, following the consideration of all public comments, adopt in final form the baselines, erosion rates, and setback lines and shall include such information in the state plan.~~

(1) The Department must establish baselines and setback lines for all geographic areas where baselines and setback lines were established on or before January 31, 2012. The baselines and setback lines must be established anew during establishment cycles that are not less than every seven (7) years, but not more than every ten (10) years following a previous establishment cycle and must be based upon the best available data. Until the Department establishes new baselines and setback lines for a geographic area, the existing baselines and setback lines for the geographic area must be used.

(2) In each new establishment cycle of the baselines and setback lines, the Department must:

(a) stagger the establishment of the baselines and setback lines by geographic area and provide a tentative schedule of establishment for each geographic area on the Department's website at least one hundred twenty (120) days prior to beginning a new establishment cycle;

(b) publish proposed locations of baselines and setback lines for a geographic area on the Department's website for public input at least one hundred twenty (120) days prior to establishing the baselines and setback lines for the geographic area;

(c) on the date of the publication of the proposed locations of baselines and setback lines for a geographic area:

(i) provide notice of the publication in a newspaper of general statewide circulation and a newspaper of local circulation in the geographic area; and

(ii) make readily available to the public, including on the Department's website, the information and raw data that the Department used to determine the locations of the proposed baselines and setback lines and explanations for these determinations;

(d) hold at least one (1) public hearing in the county or municipality of a geographic area at least ninety (90) days prior to establishing the baselines and setback lines for the geographic area; and

(e) accept and review data up to thirty (30) days prior to establishing baselines and setback lines for a geographic area to determine if a proposed baseline or setback line for the geographic area should be revised.

(3) Upon the publication of the tentative schedule established under R.30-14.E(2)(a), a municipality, county, agency, or organization undertaking a beach renourishment project may submit a request to the Department, within the one hundred twenty (120)-day notice period, to revise the establishment date for

the baseline and setback line in its geographical area. The Department may revise the establishment schedule if submitted information demonstrates the following:

(a) the municipality, county, agency, or organization has an issued Department permit in effect for a beach renourishment project, or an issued Department coastal zone consistency certification associated with a federal beach renourishment project;

(b) the request does not extend the establishment date outside of the establishment cycle timeframe set forth by R.30-14.E(1);

(c) the municipality, county, agency, or organization has encumbered funds to complete the beach renourishment project; and

(d) the municipality, county, agency, or organization will start construction of the beach renourishment project within one (1) year of the initiation of the new establishment cycle.

(4) If the construction of the qualifying beach renourishment project under R.30-14.E(3)(d) has not started within one (1) year of the initiation of the new establishment cycle, the Department must establish the baselines and setback lines using the best available scientific and historical data within the required timeframes under R.30-14.E(1).

Delete the text of R.30-14.F and reserve section to read:

~~F. Procedures for Appealing Baselines and Erosion Rates [Section 48-39-280(E)].~~

~~(1) Any landowner claiming ownership of affected property who feels that the final or revised setback line, baseline, or erosion rate as adopted is in error, upon submittal of substantiating evidence, within one year of the revision date, must be granted a review of the setback line, baseline, or erosion rate, or a review of all three. The Department shall hear all requests for review. The process is as follows:~~

~~(a) Upon receipt of a property owner's request for review of the setback, baseline, or erosion rate, a request will be made of the property owner to provide the Department with substantiating evidence, as required in Section 48-39-280(E). If the property owner does not respond or if there is no evidence at all to support the request, a letter will be sent to the property owner denying the request.~~

~~(b) If the Department agrees with the property owner that the lines are in error, the lines will be moved.~~

~~(c) If the Department disagrees with the property owner, and believes that the location of the lines is correct, the property owner will be notified in writing. Any appeal of the Department's decision under this section shall be made to the Administrative Law Judge Division.~~

~~(2) Appeals are governed by R.30-6.~~ [Reserved]

Delete the text of R.30-14.G and reserve section to read:

G. ~~Procedure for Movement of Baseline After Renourishment.~~

~~(1) The Department must receive a petition from the local government; or the landowners with notice to the local government, before the baseline can be moved pursuant to Section 48-39-280(A)(4). The petition cannot be submitted until the permitted beach nourishment project, which must have a minimum five-year design life, has been completed. The local government must certify to the Department that the proposal to~~

~~move the baseline is consistent with the objectives and policies of its local comprehensive beachfront management plan.~~

~~(2) Petitioner must demonstrate an ongoing commitment to fund a future renourishment project with the same or greater design life than the original project using an acceptable funding option.~~

~~(3) The Petitioner must prove that it possesses or has obtained all necessary legal authority to perform the nourishment project in the future, excluding environmental regulatory permits.~~

~~(4) Petitioner must submit survey data in the following format to demonstrate the beach has been stabilized by the nourishment project:~~

~~(a) A minimum of three sets of survey data from the stations (monuments) designated in the project permit must be submitted. This will include all stations within the construction limits (maximum allowable profile spacing is 1,000 feet) and stations within 2,000 feet of each end of the project. These surveys will be taken at three month intervals, beginning at the time of project construction completion.~~

~~(b) Semi-annual surveys of the project beach during years two and three after project construction must be performed and submitted to the Department to document beach stability.~~

~~(5) The Department will evaluate the survey data to determine beach stability. Stability is defined in (10) below. If the beach has not stabilized in the first six months following construction, additional subsequent surveys will be evaluated to determine stability.~~

~~(6) The project must be constructed according to the permit design at an elevation which will maintain a dry sand beach. The maintenance of the dry sand beach will be evaluated in the same manner as stability, using the survey data.~~

~~(7) The Petitioner must show an ongoing financial commitment to renourishment which will stabilize and maintain the dry sand beach at all stages of the tide for the foreseeable future. The Department defines foreseeable future as at least ten years from the date the original project achieved stability.~~

~~(8) The Department will move the baseline when all of the above criteria have been met. The new baseline will be located on the landward edge of the existing erosion control device or at a position determined by the Department using the method described in Section 48-39-280(A)(1).~~

~~(9) No new construction may occur in the area between the former baseline and the new baseline for three years after the initial beach nourishment project has been completed, unless allowed by special permit. The project is "completed" when it has stabilized in the manner described in (10) below. Reconstruction of habitable structures and pools is not considered new construction for purposes of this section. Additions are considered new construction.~~

~~(10) The following definition will be used by the Department to define "stability": A renourished beach is stabilized when field observations and quarterly surveys of the project beach, conducted for a minimum of six months following construction completion, demonstrate only normal long-term erosion patterns and losses are affecting the nourished beach. The Department may consider any or all of the following in determining stability: profile characteristics and changes (volumetric and contour changes) and sediment analyses.~~ [Reserved]

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 30

Statutory Authority: 1976 Code Sections 48-39-10 et. seq.

Notice of Drafting:

The Department of Health and Environmental Control ("Department") proposes amending R.30-1, Statement of Policy, and R.30-14, Administrative Procedures, the Department's Coastal Division regulations. Interested persons may submit comment(s) on the proposed amendments to Liz Hartje of the Office of Ocean and Coastal Resource Management, S.C. Department of Health and Environmental Control, 1362 McMillan Avenue, Suite 400, Charleston, S.C., 29405, or by email at hartjeen@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on May 28, 2019, the close of the draft comment period.

Synopsis:

The Department proposes to amend R.30-1.D.(4) and (43), and R.30-14.E., F., and G., to incorporate state statutory changes. Act 173 of 2018, the Beachfront Management Reform Act, requires the Department to establish the position of the baselines and setback lines during establishment cycles that are not less than every seven years, but not more than every ten years following a previous establishment cycle and must be based upon the best available data. The purpose of these jurisdictional lines is to delineate the extent of the Department's direct permitting authority for activities within the defined beaches and beach/dune system critical areas.

Act 173 of 2018, the Beachfront Management Reform Act, establishes the position of the jurisdictional baselines and setback lines for the 2018 establishment cycle. Act 173 also includes a section that requires the Department to promulgate regulations to implement provisions of the act, including regulations that the Department will use to locate a primary oceanfront sand dune. The Department convened a Beachfront Jurisdictional Line Stakeholder Workgroup in 2018 to provide input into this process.

The proposed amendments will be based on final recommendations of the workgroup and associated public engagement and input. The proposed amendments will provide clarity and standards to be utilized in the establishment of the state's beachfront jurisdictional lines. Proposed amendments will also modify specific procedures related to appeals and movement of the jurisdictional lines to comply with Act 173 of 2018 and Act 197 of 2016, Coastal Zone Critical Areas.

The Department may also include stylistic changes, such as corrections for clarity and readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

(x) ACTION/DECISION
( ) INFORMATION

Date: September 12, 2019

To: S.C. Board of Health and Environmental Control

From: Bureau of Environmental Health Services

Re: Notice of Proposed Regulation Amending R.61-32, *Soft Drink and Water Bottling Plants*, and Repealing R.61-54, *Wholesale Commercial Ice Manufacturing.*

I. Introduction

The Bureau of Environmental Health Services (Bureau) proposes the attached Notice of Proposed Regulation amending R.61-32, *Soft Drink and Water Bottling Plants*. The Bureau further proposes revising the requirements of R.61-54, *Wholesale Commercial Ice Manufacturing*, and merging it into R.61-32, *Soft Drink and Water Bottling Plants*. This entails repealing R.61-54, *Wholesale Commercial Ice Manufacturing* and adding its amended requirements to R.61-32, *Soft Drink and Water Bottling Plants*. The Bureau presents this proposal for publication in the September 27, 2019, *South Carolina State Register* (*State Register*). Legal authority resides in 1976 Code Sections 44-1-140 and 44-1-150, which enables the Department of Health and Environmental Control (Department) to promulgate regulations for the operation of bottling plants and similar businesses. Furthermore, Section 44-1-150 allows for the enforcement of orders related to violations of these regulations. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments and repeal. R.61-32 was last amended in 2004 and R.61-54 was last amended in 2008.

II. Facts

1. The purpose of R.61-32, *Soft Drink and Water Bottling Plants*, and R.61-54, *Wholesale Commercial Ice Manufacturing*, is to safeguard public health and provide consumers safe, unadulterated soft drinks, bottled water, and wholesale ice products manufactured in South Carolina to be sold and distributed both in state and out of state. These regulations govern the production, processing, storing, labeling, transportation, and distribution of soft drinks, bottled water, and wholesale ice products. The current regulations are based on Title 21, *Food and Drugs,* Part 110 *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food* of the Code of Federal Regulations (CFR) (21 CFR Part 110), which has now been replaced by 21 CFR Part 117 *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food*. The new federal regulation updates good manufacturing processes and incorporates new preventive controls for minimizing or preventing food safety hazards.

2. The Bureau proposes amending the provisions of R.61-32 and R.61-54 to incorporate standards of the new federal regulation. The structure of the federal regulation also facilitates combining provisions governing manufactured water-based products into one streamlined regulation, instead of two separate regulations with repetitive content.

3. To achieve this more functional, streamlined regulation, the Department proposes repealing R.61-54 and combining its revised provisions into R.61-32. This also includes amending the title of R.61-32 to "Wholesale Bottled Water, Soft Drinks, and Ice Manufacturing." The proposed amendments also include other changes not required by federal law, including additions, updates, and clarifications to administrative requirements, enforcement requirements, and definitions, as well as other changes deemed necessary by the Department to improve the overall clarity, organization, and quality of the regulation.

4. The Department had a Notice of Drafting published in the April 26, 2019, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments by the May 28, 2019, close of the public comment period.

5. The Bureau held a stakeholder meeting on July 24, 2019, in Columbia. The Bureau emailed information for meeting attendance to all permitted facilities, along with a proposed draft of the regulation to facilitate discussion. The Department also posted the information and draft regulation on the DHEC Manufactured Food web page to reach as broad an audience as possible.

6. Appropriate Department staff conducted an internal review of the proposed amendments and repeal on July 29, 2019.

7. The proposed amendments to these regulations serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements. In addition to clarification and updating of state-specific regulatory provisions, these proposed amendments incorporate current federal standards, which have replaced preexisting federal standards upon which the Department's existing, unrevised regulations are based. This serves to reduce administrative burdens on the regulated community by facilitating streamlined inspections and compliance under both state and federal requirements.

III. Request for Approval

The Bureau of Environmental Health Services respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 27, 2019, *State Register*.

Renee G. Shealy, Chief
Bureau of Environmental Health Services

Myra C. Reece, Director
Environmental Affairs

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the April 26, 2019, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-32, *Soft Drink and Water Bottling Plants,* and R.61-54, *Wholesale Commercial Ice Manufacturing.*

September 12, 2019

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-140 (4) and 44-1-150

61-32. Soft Drink and Water Bottling Plants.
61-54. Wholesale Commercial Ice Manufacturing.

Preamble:

The purpose of R.61-32, Soft Drink and Water Bottling Plants, and R.61-54, Wholesale Commercial Ice Manufacturing, are to safeguard public health and provide consumers safe, unadulterated soft drinks, bottled water, and wholesale ice products manufactured in South Carolina to be sold and distributed both in state and out of state. These regulations govern the production, processing, storing, labeling, transportation, and distribution of soft drinks, bottled water, and wholesale ice products. The regulations are based on Title 21, Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food of the Code of Federal Regulations (CFR) (21 CFR Part 110).

The Department of Health and Environmental Control (Department) last amended R.61-32 in 2004 and R.61-54 in 2008. Earlier this year, 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food was replaced by 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food. There have been numerous changes in the manufactured food industry, including changes to food handling practices, food equipment technology, and food preparation processes, making R.61-32 and 61-54 outdated. The new federal regulation updates good manufacturing processes and incorporates new preventive controls for minimizing or preventing food safety hazards.

The Department proposes amending the provisions of R.61-32, Soft Drink and Water Bottling Plants, and R.61-54, Wholesale Commercial Ice Manufacturing to incorporate standards of the new federal regulation. The structure of the federal regulation also facilitates combining provisions governing manufactured water-based products into one streamlined regulation, instead of two separate regulations with repetitive content. To achieve this more functional, streamlined regulation, the Department proposes repealing R.61-54 and combining its revised provisions into R.61-32. This also includes amending the title of R.61-32 to "Wholesale Bottled Water, Soft Drinks, and Ice Manufacturing." The proposed amendments also include other changes not required by federal law, including additions, updates, and clarifications to administrative requirements, enforcement requirements, and definitions, as well as other changes deemed necessary by the Department to improve the overall clarity, organization, and quality of the regulation. These changes include stylistic changes such as corrections for clarity and readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments and repeal.

The Department had a Notice of Drafting published in the April 26, 2019, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments and Repeal:

R.61-54 is stricken in its entirety and repealed.

R.61-32 is stricken in its entirety and replaced with the combined, revised text of R.61-32 and R.61-54. The following discussion of the proposed amendments and repeal details specific changes to R.61-32 and R.61-54's existing, unrevised regulatory language.

The Table of Contents reflects the new proposed language. Some sections have been moved and/or renamed to streamline the regulation and to reflect changes in enforcement and administrative processes.

Replaced in all sections and titles, "soft drink and water bottling plants" with "wholesale bottled water, soft drinks, and ice manufacturing" where applicable.

Formatting was changed to reflect the lettering of sections as opposed to numbering to harmonize with other manufactured food regulations.

In Section I. PURPOSE

No changes

In Section II. SCOPE

No changes

In Section III. DEFINITIONS, the following changes apply:

Deleted: Definitions for "Shall" "Should or May," "Standard of Identity", "Standard of Quality", "Undesirable Microorganisms", and "Unexposed Packaged Food" as unnecessary or unused. Deleted "Food-contact Surface" and "Easily Cleanable" as redundant to definitions in 21 CFR 117.3.

61-32.III.B. Added: a.- g. to clarify what constitutes adulteration.

61-32.III.C: Amended: to consistently define the meaning of approved under Bureau regulations.

61-32.III.E. Amended: to clarify this definition is not limited to bottled water plants.

61-32.III.J. Added: Business day to provide clarity on compliance time requirements.

61-32.III.L. Amended: to simplify the purpose of the code of federal regulations.

61-32.III.S. Amended: "Employee" to clarify who is defined by this role.

61-32.III.U. Added: "Exclusion" to clarify that it is related to preventing an employee from entering or working in a manufactured grade dairy products plant or distribution station.

61-32.III.V. Added: "FDA" to clarify that this refers to the United States Food and Drug Administration.

61-32.III.W. Amended: “Food” to be as defined in 21 CFR 117.3.

61-32.III.Y. Added: “Ice” from R.61-54.

61-32.III.Z. Added: “Ice Vending Machines” from R.61-54.

61-32.III.AA. Added: to clarify and define the conditions that are related to imminent health hazards.

61-32.III.BB. Added: “Law” to clarify that it applies to local, state and federal laws.

61-32.III.CC.-FF. Amended: Previous definitions for bottled water, soft drink and ice manufacturers to reflect new definitions for manufactured bottled water, soft drink and ice products, distribution stations, distributors, manufacturers, plants and retailers.

61-32.III.GG. Amended: “Microorganisms” as defined in 21 CFR 117.3.

61-32.III.JJ. Added: “Packaged Ice” from R.61-54.

61-32.III.KK. Added: “Pathogen” to define that it is a microorganism of public health concern.

61-32.III.LL and MM. Added: “Permit” and “Permit Holder” to clarify for compliance and documentation purposes.

61-32.III.OO. Amended: “Pest” to clarify that it refers to any objectionable animals and insects.

61-32.III.QQ. Added: “Premises” to clarify all of the potential areas covered under this regulation.

61-32.III.RR. Added: “Restriction” to clarify that this is related to limiting the activities of an employee as it relates to working in a manufactured grade dairy products plant or distribution station.

61-32.III.SS. Added: “Retail Food Establishment” to clarify that these are establishments that sell directly to the end consumer.

61-32.III.WW. Added: Risk to clarify that this is related to a public health hazard.

61-32.III.XX. Amended: “Sanitize” to reflect the current science related to destroying pathogens on surfaces.

61-32.III.CCC. Added: “Unexposed packaged food” to clarify that it is packaged food that has not been exposed to the environment.

Added: That additional related definitions are found in 21 CFR 117.3.

In Section IV. ADULTERATED OR MISBRANDED BOTTLED WATER, SOFT DRINKS, OR ICE, the following changes apply:

61-32.IV.A. Added: the entire section to address adulteration or misbranding of bottled water, soft drinks and ice.

61-32.IV.B. Added: to address when a hold order may be issued.

61-32.IV.C. Added to address suspension of permits when hold orders are violated.

61-32.IV.D. Added: to address condemnation of food.

61-32.IV.E. Added: to address notice and issuance of hold orders.

61-32.IV.F. Added: to address examination of products for adulteration or misbranding and the storage of products under a hold order.

61-32.IV.G. Added: to address products adulterated by drugs or poisonous substances.

In Section V. COMPLIANCE PROCEDURES, the following changes apply:

Relocated this entire section from previous Section IX Enforcement.

61-32.V.A. Amended: to clarify permit requirements.

61-32.V.B.1. Amended: to add violation of an order issued by the Department to this section.

61-32.V.B.2. Amended: to clarify requirements governing summary permit suspension.

61-32.V.B.4. Amended: to clarify timeframe for re-inspection or sampling.

61-32.V.C.1. Amended: to add violation of an order issued by the Department to this section.

61-32.V.C.2. Amended: to remove section that referred to hearing procedures and added information to include clarification of inspection and enforcement history as it relates to non-compliance.

61-32.V.C.3. Amended: to clarify process for re-applying for a new permit once a permit is revoked.

In Section VI. LABELING, the following changes apply:

61-32.VI. Amended: deleted outdated language and added that products must be labeled according to 21 CFR Part 101.

In Section VII. INSPECTION OF BOTTLED WATER, SOFT DRINK AND ICE PLANTS AND DISTRIBUTION STATIONS, the following changes apply:

61-32.VII.B. Amended: to adjust frequency of inspections to be determined by the risk level of the product.

61-32.VII.C. Amended: to allow for electronic or paper inspection reports and clarify delivery method.

61-32.VII.E. Added: to provide for the protection of trade secrets.

In Section VIII. THE EXAMINATION OF BOTTLED WATER, SOFT DRINKS AND ICE

Moved and created this new section from previous Section VII. Production and Process Controls A.3. and updated sampling protocols.

In Section IX. BOTTLED WATER, SOFT DRINK AND ICE PLANTS AND DISTRIBUTION STATIONS

61-32.IX.A. Amended: to clarify who must have an approved public water supply and the examination and records requirements.

61-32.IX.I Amended: Relocated and combined all previous sections relating to the sanitation, production and processing of these products. This included deleting sections on sanitation and replacing with new language that requires compliance with requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart C - Hazard Analysis and Risk Based Preventive, Subpart D - Modified Requirements, Subpart F - Requirements Applying to Records That Must Be Established and Maintained, and Subpart G - Supply-Chain Program.

Renumbered remaining sections.

In Section X. SUBMISSION OF PLANS.

No changes

In Section XI. RECIPROCITY.

61-32.XI. Amended: clarified and simplified requirements for recognizing out of state or country products.

In Section XII. OUT-OF-STATE BOTTLED WATER IMPORTS.

No changes

In Section XIII. RECALL.

61-32.XIII. Amended: to reference 21 CFR Part 117.139 if applicable and, if not applicable, state the requirements for a procedure for developing a recall plan.

In Section XIV. EQUIPMENT AND FACILITES IN OPERATION PRIOR TO JULY 1, 2020

61-32.XIV. Amended: Re-titled and replaced the content of this entire section with new content on allowing equipment and facilities approved under previous versions of this regulation to be accepted as long as they are capable of being maintained in a sanitary condition and are not creating a health hazard. Renumbered remaining sections.

In Section XV. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED.

61-32.XV. Amended: updated the language in this section to clarify when and how to restrict and exclude ill food employees.

In Section XVI. ENFORCEMENT PROVISIONS.

61-32.XVI. Amended: replaced the entire section with language that reflects current laws

In Section XVII. SEVERABILITY CLAUSE.

No changes

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments and repeals to Sandra Craig of the Bureau of Environmental Health Services; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; craigsd@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 28, 2019, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments and repeals during its December 12, 2019, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agency/docs/AGENDA.PDF.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/.

Preliminary Fiscal Impact Statement

There are no anticipated new costs associated with the implementation of this regulation to the state or its political subdivisions.

Statement of Need and Reasonableness

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-32, Soft Drink and Water Bottling Plants, and 61-54, Wholesale Commercial Ice Manufacturing.

Purpose: This amendment strikes the text of the existing regulations in total, repeals the text of R.61-54, and combines the revised text of both to align with current applicable federal standards. The existing regulations are based on 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, which has been replaced with 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food. The new federal regulation updates good manufacturing processes to be implemented by the regulated community and also incorporates new preventive controls for minimizing or preventing food safety hazards.

Legal Authority: 1976 Code Sections 44-1-140 and 44-1-150

Plan for Implementation: The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to these proposed amendments and repeals. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendments and repeals and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The purpose of R.61-32, Soft Drink and Water Bottling Plants, and R.61-54, Wholesale Commercial Ice Manufacturing, is to safeguard public health and provide consumers safe, unadulterated soft drinks, bottled water, and wholesale ice products manufactured in South Carolina to be sold and distributed both in state and out of state. These regulations govern the production, processing, storing, labeling, transportation, and distribution of soft drinks, bottled water, and wholesale ice products. The regulations are based on Title 21, Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food of the Code of Federal Regulations (CFR) (21 CFR Part 110).

The Department of Health and Environmental Control (Department) last amended R.61-32 in 2004 and R.61-54 in 2008. Earlier this year, 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food was replaced by 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food. There have been numerous changes in the manufactured food industry, including changes to food handling practices, food equipment technology, and food preparation processes, making R.61-32 and 61-54 outdated. The new federal regulation updates good manufacturing processes to be implemented by the regulated community and incorporates new preventive controls for minimizing or preventing food safety hazards.

The Department proposes amending the provisions of R.61-32 and R.61-54 to incorporate the standards of the new federal regulation. The structure of the federal regulation also facilitates combining provisions governing manufactured water-based products into one streamlined regulation into one streamlined regulation, instead of two separate regulations with repetitive content.

The proposed amendments to these regulations serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements. In addition to clarification and updating of state-specific regulatory provisions, these proposed amendments incorporate current federal standards which have replaced preexisting federal standards upon which the Department's existing, unrevised regulations are based. This serves to reduce administrative burdens on the regulated community by facilitating streamlined inspections and compliance under both state and federal requirements.

DETERMINATION OF COSTS AND BENEFITS:

There are no anticipated new costs associated with the implementation of this regulation. The proposed amendments will benefit public health by ensuring safe, unadulterated bottled water, soft drinks, and wholesale ice products from manufacturing plants and throughout the distribution chain. The proposed amendments to these regulations serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements. Furthermore, industry will benefit by only having an aligned set of rules to comply with for federal inspections that may be conducted by the FDA, those conducted by the Department for the FDA, and those conducted for the state under this regulation. Such alignment also allows for facilities to undergo one inspection, conducted by the Department under this regulation, to satisfy both federal and state oversight. The amendments also combine provisions governing manufactured water-based products into one streamlined regulation, instead of two separate regulations with repetitive content.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Implementation of this regulation will not compromise the protection of the environment or the public health. The proposed regulation will help to ensure that consumers are receiving safe, unadulterated bottled water, soft drinks, and wholesale ice products. The amendment of R.61-32 to conform to the most recent federal regulation provides effective means of reducing the risks of foodborne illnesses within food manufacturing plants, thus protecting consumers and industry from potentially devastating public health consequences and financial loss. Incorporation of the Food Safety Modernization Act compliant 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food and the new preventive controls provision for minimizing or preventing food safety hazards allows for better training and understanding of risk by those in charge of food safety in processing plants.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There will be no adverse effect on the environment if the regulations are not implemented.

Failure to adopt these amendments would prevent implementation of the latest sanitary standards and a comprehensive approach to food safety management needed in addressing food protection in the manufactured water-based products industry. This could have a detrimental effect on the health of South Carolina's citizens and visitors.

Statement of Rationale:

The Department proposes these amendments to ensure safe, unadulterated bottled water, soft drinks, and wholesale ice products from manufacturing plants and throughout the distribution chain. Furthermore, the amendments allow for one inspection, conducted by the Department under this regulation, to satisfy both federal and state oversight. The amendments also combine provisions governing manufactured water-based products into one streamlined regulation, instead of two separate regulations with repetitive content.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

~~61-32. Soft Drink And Water Bottling Plants.~~

~~(Statutory Authority: S.C. Code Ann. Sections 44-1-140(4); 1-23-10; 1-23-110 (1976, as amended))~~

~~CONTENTS:~~
~~SECTION I. PURPOSE.~~
~~SECTION II. SCOPE.~~
~~SECTION III. DEFINITIONS.~~
~~SECTION IV. PERSONNEL.~~
~~SECTION V. GROUNDS, BUILDINGS AND FACILITIES.~~
~~SECTION VI. EQUIPMENT AND UTENSILS.~~
~~SECTION VII. PRODUCTION AND PROCESS CONTROLS.~~
~~SECTION VIII. EXAMINATION AND COMDEMNATION OF UNWHOLESOME OR CONTAMINATED~~
~~RAW MATERIALS OR FINISHED PRODUCT.~~
~~SECTION IX. ENFORCEMENT PROCEDURES~~

~~SECTION I. PURPOSE~~

~~This regulation sets forth minimum health standards, procedures and practices to ensure that soft drinks and bottled waters, are manufactured in South Carolina in a safe and wholesome manner.~~

~~SECTION II. SCOPE~~

~~This regulation shall apply to all persons in South Carolina who manufacture or bottle soft drinks and bottled waters, sold for human consumption in South Carolina.~~

~~SECTION III. DEFINITIONS~~

~~ADEQUATE – shall mean substantial compliance with acceptable health standards, procedures and practices.~~

~~ADULTERATED or ADULTERATION – the presence or addition of any harmful or unwholesome substance, article, object, or other ingredients which may dilute or lower the quality of the beverage involved or any substance which is prohibited by law or regulation in a soft drink or bottled water.~~

~~APPROVED – acceptable to the Department based on a determination as to conformance with applicable standards and good public health practice.~~

~~APPROVED LABORATORY – a laboratory approved by the Department or certified by the U.S. Environmental Protection Agency (EPA), or certified (accredited) by a third-party organization acceptable to the Department.~~

~~APPROVED SOURCE – when used in reference to a bottled water plant's product water or water used in the plant's operations, means the source of the water whether it be from a spring, artesian well, drilled well, public or community water system, or any other source that has been inspected and the water sampled, analyzed, and found of a safe and sanitary quality with or without treatment, and approved by the Department in accordance with Regulation 61-58, State Primary Drinking Water Regulations.~~

~~ARTESIAN WATER – bottled water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer. Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to the Department that the water level stands at some height above the top of the aquifer.~~

~~BOTTLED WATER – water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. It does not include those food ingredients that are declared in ingredient labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "sparkling water," and "tonic water."~~

~~BOTTLING – filling, capping, packaging or enclosing in containers.~~

~~BOTTLING PLANT – any establishment involved in the manufacturing or packaging of soft drinks and bottled waters.~~

~~BULK WATER – source water collected at an approved site remote from the bottling plant and transported to the bottling plant for further processing and bottling.~~

~~CODE OF FEDERAL REGULATION (CFR) - a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.~~

~~CONTAINER - any material used for the packaging of soft drinks and bottled waters, whether of glass, plastic, metal, paper or any combination thereof.~~

~~DEMINERALIZED WATER - bottled water which is produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the United States Pharmacopoeia and specified by the U. S. Food and Drug Administration (FDA) in 21 CFR Section 165.110.~~

~~DEIONIZED WATER - bottled water that has been produced by a process of deionization and that meets the definition of "purified water" in the United States Pharmacopoeia and specified by the FDA in 21 CFR Section 165.110.~~

~~DEPARTMENT - the South Carolina Department of Health and Environmental Control acting through its authorized representatives.~~

~~DISTILLED WATER - bottled water which has been produced by a process of distillation and meets the definition of "purified water" in the United States Pharmacopoeia and specified by FDA in 21 CFR Section 165.110.~~

~~DRINKING WATER - water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents.~~

~~EASILY CLEANABLE - surfaces that are readily accessible and made of such materials and finishes and fabricated in such a way that residue may be effectively removed by normal cleaning methods.~~

~~EMPLOYEE - any person in a bottling plant engaged in the mixing of syrups, filling of containers, or any other capacity which brings them into contact with ingredients, containers, or equipment used in the manufacturing and packaging of soft drinks and bottled waters.~~

~~EQUIPMENT - all machinery, utensils, conveyors, containers, cases, and other articles used in the manufacturing of soft drinks and bottled waters.~~

~~FOOD - raw materials and ingredients.~~

~~FOOD-CONTACT SURFACE - the surface of any object coming into direct contact with ingredients and finished products during storage and manufacture. This shall include any surface upon which the product routinely may drip, drain, or be drawn into, as part of normal processing.~~

~~GROUND WATER - water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. Ground water must not be under the direct influence of surface water.~~

~~MICROORGANISMS - mean yeast, molds, bacteria and viruses and include, but are not limited to, species having public health significance.~~

~~MINERAL WATER - bottled water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more boreholes or springs, originating from a geologically and physically protected underground water source. Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.~~

~~NATURAL WATER - bottled spring, mineral, artesian, or well water which is derived from an underground formation or water from surface water that only requires minimal processing, is not derived from a municipal system or public water supply, and is unmodified except for limited treatment (e.g., filtration, ozonation or equivalent disinfection process).~~

~~PERSON - any individual, plant operator, partnership, company, corporation, trustee, association, or a public or private entity.~~

~~PEST - any animals or insects including, but not limited to, birds, rodents, flies and larvae.~~

~~PURIFIED WATER - bottled water produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.~~

~~REMODELED - any enlarging, replacing of floors, walls or ceilings, or changing in any respect, the structure at which a soft drink or water bottling plant is housed; provided, however, this shall not apply to repainting or refinishing of floors or walls.~~

~~REVERSE OSMOSIS WATER - bottled water that is produced by a process of reverse osmosis and that meets the definition of "purified water" in the United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.~~

~~SANITIZE - to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance.~~

~~SHALL - the item or condition discussed is mandatory.~~

~~SHOULD or MAY - the item or condition discussed is preferred but not mandatory.~~

~~SOFT DRINK - any nonalcoholic flavored carbonated beverage, soda or soda water, fruit juice, fruit drink, nonalcoholic still beverage, and seltzer or club soda.~~

~~SPARKLING BOTTLED WATER - bottled water that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at the emergence from the source. Manufacturers may add carbonation to previously noncarbonated bottled water products and label such water appropriately (e.g. sparkling spring water).~~

~~SPRING WATER - bottled water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water must comply with the FDA standard of identity in 21 CFR 165.110.~~

~~STANDARD OF IDENTITY - the FDA Standard of Identity for bottled water as set forth in 21 CFR 165.110.~~

~~STANDARD OF QUALITY - the FDA Standards of Quality for bottled as set forth in 21 CFR165.110.~~

~~STERILE WATER – bottled water that meets the requirements under "Sterility Tests" <71> in the current United States Pharmacopoeia and specified by FDA in 21 CFR 165.110.~~

~~UNDESIRABLE MICROORGANISMS – those microorganisms which are considered to be of public health significance, which subject food to decomposition, which indicate that food is contaminated with filth, or which otherwise may cause food to be adulterated.~~

~~WELL WATER – bottled water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer.~~

~~SECTION IV. PERSONNEL~~

~~A. DISEASE CONTROL~~

~~Any person who by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which may contribute to the reasonable possibility of food, food-contact surfaces, or foodpackaging materials becoming contaminated, shall be excluded from any operations expected to result in such contamination, until the condition is corrected. All personnel shall be instructed to report such health conditions to their supervisors.~~

~~B.CLEANLINESS~~

~~All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. Methods for maintaining cleanliness to prevent food contamination include, but are not limited to:~~

~~1. Wearing outer garments suitable for the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.~~

~~2. Maintaining adequate personal cleanliness.~~

~~3. Washing hands thoroughly (and sanitizing, if necessary, to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. Signs shall be posted reminding employees to wash their hands before returning to work.~~

~~4. Removing all insecure jewelry or other objects which might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it should be covered by material that can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.~~

~~5. Maintaining gloves used in food handling in an intact, clean, and sanitary condition. These gloves should be of an impermeable material.~~

~~6. Where appropriate, wearing in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.~~

~~7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.~~

~~8. Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.~~

~~9. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.~~

~~C. EDUCATION AND TRAINING~~

~~Personnel responsible for identifying sanitation failures or food contamination should have a background in education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food protection principles, and should be informed of the danger of poor personal hygiene and unsanitary practices.~~

~~D. SUPERVISION~~

~~Responsibility for ensuring compliance by all personnel with all requirements of this section shall be clearly assigned to competent supervisory personnel.~~

~~SECTION V. GROUNDS, BUILDINGS AND FACILITIES~~

~~A. GROUNDS~~

~~The grounds around a bottling plant under the control of the operator shall be kept in such condition to protect against the contamination of its products. The methods for adequate maintenance of grounds include, but are not limited to:~~

~~1. Properly storing equipment, removing litter and waste, and cutting weeds or grass in the immediate vicinity of plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.~~

~~2. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.~~

~~3. Adequately draining areas that may contribute to the contamination of food by seepage, foot-borne filth, or providing a breeding place for pests.~~

~~4. Operating waste treatment and disposal systems in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.~~

~~B. BUILDING CONSTRUCTION AND DESIGN~~

~~Bottling plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes and to prevent drip and condensation from fixtures, ducts and pipes from contaminating foods, food-contact surfaces or food containers. Sufficient space shall be provided for the placement of equipment and storage of materials as deemed~~

~~necessary for the proper maintenance of sanitary operations and production of safe food. Bottling plants shall meet, but not be limited to, the following:~~

~~1. REQUIRED ROOMS~~

~~(a) Whenever ingredients are mixed, a separate room (commonly called a syrup or blend room) or separate area of the filling room shall be provided for this purpose. This room or separate area of the filling room shall be used only for mixing ingredients and storage of mixed batches.~~

~~(b) A separate room shall be provided for filling and sealing containers (commonly called a filling or bottling room). This room shall contain only necessary filling, sealing, electronic inspection, coding and labeling equipment. Only the exit end of the bottle washing machine shall open into this room through a tight-fitting wall. If approved by the Department, the mixing of ingredients and storage of mixed batches can be conducted in this room.~~

~~2. FLOORS~~

~~(a) The floors of the syrup and filling rooms shall be constructed of concrete or equally impervious, easily cleanable material, and shall be kept clean, in good repair, and properly sloped to trapped drains to prevent pools of standing water after flushing. Integral coved juncture bases should be provided in these areas.~~

~~(b) The floors of storage, packaging and accessory rooms shall be easily cleanable, and be kept clean and in good repair at all times.~~

~~3. WALLS AND CEILINGS~~

~~(a) The walls and ceilings in the syrup and filling rooms shall be smooth, washable, light colored, and shall be kept clean and in good repair at all times. Lay-in ceiling tile panels may be used if they are designed to be easily removable for cleaning and replacement, as needed.~~

~~(b) The walls and ceilings of storage, packaging and accessory rooms or areas shall be of sound construction and kept clean and in good repair at all times.~~

~~4. LIGHTING~~

~~(a) Adequate lighting shall be provided in all areas of the plant. A minimum of 20 foot-candles of light should be provided in all working areas, and a minimum of 10 foot-candles in all storage areas.~~

~~(b) Adequate protection from glass breakage and falling debris shall be provided for all light bulbs and fixtures located over exposed food or unsealed containers in any step of preparation.~~

~~5. VENTILATION~~

~~(a) Adequate ventilation or control equipment shall be provided to minimize odors, vapors and moisture and to keep excessive carbon dioxide, ozone, and other processing gases, from accumulating in areas where soft drinks and bottled waters are manufactured.~~

~~(b) Pressurized ventilating systems shall have a filtered air intake.~~

~~(c) Fans and other air-moving equipment shall be located and operated in a manner minimizing the potential for contaminating food and unsealed containers.~~

~~6. DOORS AND WINDOWS~~

~~(a) All openings into the syrup and filling rooms shall be adequately protected against the entrance of dust and insects by tight-fitting, self-closing doors, closed windows, screening, air curtains, vinyl or rubber strip curtains, or by other means approved by the Department.~~

~~(b) Screens for windows, doors, skylights, transoms, intake and exhaust air ducts, and other openings into the syrup and filling rooms shall be tight-fitting and free of breaks. Screening materials shall not be less than sixteen mesh to the inch.~~

~~(c) Openings for conveyor lines into the filling room shall be as small as possible.~~

~~(d) Solid doors for the syrup and filling rooms shall be outward opening unless accompanied by selfclosing, outward-opening screen doors.~~

~~C. SANITARY FACILITIES AND CONTROLS~~

~~Each bottling plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to, the following:~~

~~1. WATER SUPPLY~~

~~(a) The water supply shall be from a public water system approved by the Department.~~

~~(b) The design, operation and maintenance of water purification systems used to further treat potable water shall be approved by the Department. They shall not be operated beyond their rated capacity and shall be maintained in a clean, sanitary condition at all times. This shall include dispensed water vending machines.~~

~~(c) Potable running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of soft drinks and bottled waters, for the cleaning of equipment, utensils, and containers, and for employee sanitary facilities.~~

~~(d) Carbonated water shall be conveyed in approved stainless steel or equal food-grade piping and not in piping of galvanized iron, lead, zinc, or other deleterious materials.~~

~~(e) All water storage and cooling tanks shall be of noncorrosive material, properly covered, air vents properly filtered, clean, free from dust both inside and outside, and the inlet and outlet so arranged as to prevent contamination during filling and emptying.~~

~~D. TRANSPORTATION OF BULK WATER.~~

~~1. Bulk water shall be from a public water system approved by the Department.~~

~~2. The means and methods of transporting bulk water shall be approved by the Department. Bulk tanks, hoses, pumps and connections used for loading, transporting and unloading water shall be sanitized. Source water for transport shall be treated with an effective disinfectant approved by the Department at an approved concentration prior to being transported.~~

~~3. Tank filling and delivery hose connections shall be cleaned and sanitized on a regular basis. The tank shall be sealed at all times except when being filled, being cleaned and sanitized and when the water is being unloaded. A record of such cleaning and sanitizing shall be maintained with the vehicle and shall be available upon request by the Department. Pumps, hoses, connections and fittings shall be capped and protected from contamination when not in use. The tank manhole shall not be used as a means of filling the tank. To prevent collapse of the tank during delivery of bulk water, the manhole may be opened but shall be provided with an air filter to prevent contamination.~~

~~4. All surfaces which come into contact with water during storage prior to transport, shall be of smooth, impervious, nonabsorbent, corrosion resistant and nontoxic material such as stainless steel of the American Iron and Steel Institute 300 Series, or equally corrosion resistant, nontoxic material. All water contact surfaces shall be free of substances which may render the water hazardous to health or which may adversely affect the flavor, color, turbidity, odor, radiological, microbiological or chemical quality of the water.~~

~~5. Bulk water transport is intended to move source water from one area to another for the purpose of treatment, packaging and human consumption. Such water shall not be dispensed directly to consumers from a bulk water transport tank or indirectly through some other vending device unless otherwise approved by the Department. In case of an emergency, such as a drinking water shortage or outage, or a contaminated water supply, treated water may be dispensed directly from a properly sanitized water transport tank.~~

~~E. DISPOSAL OF WASTES.~~

~~1. All liquid wastes shall be disposed of by connection to a public sewer or as approved by the Department.~~

~~2. Rubbish, refuse, and garbage shall be so handled, stored and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces and water supplies.~~

~~F. PLUMBING.~~

~~Plumbing shall meet all applicable state and local plumbing laws, ordinances and regulations, and shall be sized, installed and maintained to:~~

~~1. Carry sufficient quantities of water to required locations throughout the bottling plant.~~

~~2. Properly convey sewage and liquid disposable waste from the bottling plant.~~

~~3. Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment, or utensils or create an unsanitary condition.~~

~~4. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.~~

~~5. Prevent backflow or back-siphonage from, or cross-connection between, piping systems discharging wastewater or sewage and piping systems carrying water for soft drink and bottled water manufacturing. This shall include adequate backflow and back-siphonage protection for water lines used to transport detergents, sanitizers, lubricants, etc.~~

~~G. TOILET FACILITIES.~~

~~1. Toilet facilities shall be approved by the Department, shall be adequate, conveniently located, accessible to employees at all times, and shall conform to applicable building and plumbing codes.~~

~~2. Toilet room floors shall be easily cleanable. Toilet room floors should be properly sloped to trapped drains.~~

~~3. Toilet room walls and ceilings shall be of sound construction. Toilet room walls shall be smooth and washable to at least a wainscot height.~~

~~4. Toilet rooms shall not open directly into the syrup or filling rooms.~~

~~5. Toilet room doors shall be self-closing.~~

~~6. Toilet rooms shall be adequately ventilated. Toilet room windows opened for ventilation shall be properly screened.~~

~~7. Toilet rooms shall be kept clean, in good repair and free of insects at all times.~~

~~8. Approved hand-washing signs shall be posted in each toilet room used by production employees.~~

~~9. Toilet tissue, soap, individual towels and trash receptacles shall be provided.~~

~~H. DRESSING ROOMS AND LOCKER AREAS.~~

~~1. If employees routinely change clothes within the bottling plant, rooms or areas shall be designated and used for that purpose and shall be kept clean and in good repair.~~

~~2. Adequate lockers or other suitable facilities shall be provided and used for the orderly storage of employee clothing and other belongings and shall be kept clean. Personnel lockers shall not be located in the syrup or filling rooms.~~

~~I. HAND-WASHING FACILITIES.~~

~~1. An adequate number of lavatories, convenient to toilet rooms and production areas, shall be provided.~~

~~2. Each lavatory shall be provided with hot and cold running water, soap and approved sanitary towels, or other approved hand-drying devices. If disposable towels are used, easily cleanable waste receptacles shall be conveniently located near the hand washing facilities.~~

~~J. SANITARY OPERATIONS.~~

~~1. GENERAL MAINTENANCE~~

~~Buildings, fixtures, and other physical facilities of the bottling plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment~~

~~maintenance and operation, or in manufacturing or processing operations shall be used or stored in the bottling plant. These materials shall be identified, used only in such manner and under conditions as will be safe for their intended uses, and stored in an approved area and manner so as to minimize the danger of contamination of food and food-contact surfaces.~~

~~2. ANIMAL AND VERMIN CONTROL~~

~~No animals or birds shall be allowed in any area of the bottling plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues. Insecticides and rodenticides shall be properly labeled and stored in a approved area and manner so as to minimize the danger of contamination of food and food-contact surfaces.~~

~~SECTION VI. EQUIPMENT AND UTENSILS~~

~~A. All bottling plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained and kept clean and in good repair. The design, construction and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal and glass fragments, contaminated water, or any other contaminants.~~

~~B. All equipment shall be so installed and maintained to facilitate the cleaning of the equipment and all adjacent spaces.~~

~~C. All food-contact surfaces shall be corrosion-resistant when in contact with food and shall be made of nontoxic materials and designed to withstand the environment of their intended use and any corrosive action by the food, cleaning compounds and sanitizing agents. Seams on food-contact surfaces shall be smoothly bonded.~~

~~D. All equipment shall be designed to prevent food-contact surfaces from being contaminated by clothing or personal contact.~~

~~E. Mixing and storage tanks shall be provided with approved tight-fitting covers which shall be kept closed when in use, except when blending is being conducted.~~

~~F. All equipment shall be constructed so that drip or condensation from fixtures, ducts, pipes, etc., does not contaminate food, food-contact surfaces or food-packaging materials.~~

~~G. All equipment that is in the manufacturing or food-handling areas and that does not come in contact with food shall be so constructed that it can be kept in a clean condition.~~

~~H. Approved washable covers shall be provided over exposed containers prior to filling and between filling and sealing in all areas where contamination is reasonable possible.~~

~~SECTION VII. PRODUCTION AND PROCESS CONTROLS~~

~~A. PROCESS CONTROLS.~~

~~1. All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging and storing of food shall be conducted in accordance with adequate sanitation principles. During~~

~~delivery of bulk ingredients in tanks, to prevent collapse of the tank, the manhole may be opened, but shall be provided with an air filter to prevent contamination.~~

~~2. Appropriate quality control operators should be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the bottling plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source.~~

~~3. Chemical, microbiological, or extraneous material testing procedures shall be used, where necessary, to identify sanitation failures or possible food contamination. All food that has become adulterated shall be rejected, or if permissible, treated or processed to eliminate the contamination.~~

~~4. Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into soft drinks and bottled waters and shall be stored under conditions that will protect against contamination and minimize deterioration.~~

~~5. Raw materials and other ingredients shall be properly labeled and stored in containers designed and constructed so as to protect against contamination.~~

~~6. Raw materials and ingredients shall be kept at such temperature and relative humidity to prevent the food from becoming adulterated.~~

~~7. The bottler shall maintain in the plant a current certification or notification of approval from the Department which shall constitute approval of the water source and which shall be available for inspection, and a copy of which shall be made available to consumers upon request.~~

~~8. Soft drink and bottled water products shall not be stored, transported, processed or bottled through equipment or lines used for any non-food product.~~

~~9. Soft drink and bottled water production, including transporting, processing, packaging, and storage shall be conducted under such conditions and controls as are necessary to minimize the potential for microbiological contamination of the finished product.~~

~~10. Bottled water shall be subject to effective germicidal treatment by ozonation or carbonation at a minimum of three volumes of carbon dioxide or other equivalent disinfection approved by the Department.~~

~~11. Weekly in-house total coliform monitoring on finished product of each bottled water product type and quarterly rinse/swab tests on bottled water containers (incoming as well as those immediately from the washer) and closures shall be performed in-house or by an approved laboratory as stipulated in 21 CFR Section 129.80. For microbiological contaminants (total coliform), analyze a representative sample from a batch or segment of a continuous production run for each bottled water product type produced by the plant.~~

~~12. Samples of source water shall be taken and analyzed by the bottled water plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every four years for radiological contaminants. Firms that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants.~~

~~13. For chemical, physical, and radiological contaminants, a representative sample from a batch or segment of continuous production run for each type of finished bottled water product produced by the plant shall be analyzed annually to assure that the product(s) complies with current FDA standards.~~

~~14. Bottled water may be used as an ingredient in beverages (e.g. diluted juices, flavored bottled waters).~~

~~15. Spring water shall be collected only at the spring or through a borehole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified and such identification shall be maintained in the company's records. Spring water collected with the use of an external force shall be from the same underground striation as the spring, as shown by a measurable hydraulic connection using a hydrogeologically valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request to the Department, using a hydrogeologically valid method, that an appropriate hydraulic connection exists between the natural orifice of the spring and the borehole.~~

~~16. Fluoride may be optionally added to bottled water within the limitations established in 21 CFR Section 165.110. Firms may manufacture nonstandardized bottled water products with ingredients such as minerals for flavor. The common usual name of the resultant product must reflect these additions.~~

~~B. CLEANING AND SANITIZING OF EQUIPMENT AND UTENSILS~~

~~All utensils and food-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Non food-contact surfaces of equipment used in the operation of bottling plants shall be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles and other debris. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and food-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruptions during which such utensils and food-contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the food-contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. All cleaning and sanitizing agents shall be free of undesirable microorganisms, shall be safe and adequate under the conditions of use, shall have labels which properly identify the contents, and shall be properly stored. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment. All cleaned and sanitized equipment and utensils shall be transported and stored to assure complete drainage and stored in a manner that protects the food-contact surfaces from contamination.~~

~~C. APPROVED METHODS OF SANITIZATION.~~

~~1. Hot water may be used if the cleaned surfaces to be sanitized are in contact with water at a temperature not less than 170ºF. for a period of not less than two minutes. In treating pipelines and fillers, the water issuing from the outlet must be a minimum of 170ºF. for a least two minutes.~~

~~2. Chlorine may be used if the cleaned surfaces to be sanitized are in contact with a solution containing not less than fifty parts per million of available chlorine as a hypochlorite and at a temperature of at least~~

~~75ºF. for not less than one minute or to an equivalent chlorine concentration/time period process approved by the Department.~~

~~3. Other methods of sanitization may be used if approved by the Department.~~

~~D. RETURNABLE CONTAINER CLEANING.~~

~~1. All returnable containers shall be adequately, mechanically washed and sanitized prior to filling. Unless the containers are sealed after washing, they shall be washed immediately prior to filling. Hand cleaning of containers is prohibited except as a preliminary to subsequent mechanical washing.~~

~~2. METAL AND GLASS CONTAINERS~~

~~(a) All metal and glass containers shall be exposed to a minimum 3% alkali solution of which not less than 60% is caustic soda (sodium hydroxide) by an approved automatic mechanical method for a period of not less than five minutes at a temperature of not less than 130ºF., or to an equivalent cleaning and sanitizing process approved by the Department.~~

~~(b) Containers shall be rinsed of all caustic soda with potable water.~~

~~3. POLYCARBONATE CONTAINERS~~

~~(a) Polycarbonate containers shall be cleaned with approved non-caustic detergents at their required concentrations by an approved mechanical method.~~

~~(b) An approved sanitizing rinse consisting of chlorine, bromine, iodine, quaternary ammonia or ozonated water at the proper approved temperature/time/concentration must follow the cleaning cycle.~~

~~4. A permanent record of key operating parameters of the container washer should be maintained. These records or logs should include, but not limited to wash temperatures, concentrations of cleaners, concentrations of sanitizers, lack of carryover of cleaners or caustic in bottles, and maintenance on the washer. Tests on cleaner/sanitizer concentrations and carryover should be carried out at start-up and regularly thereafter throughout the shift. All maintenance on washer should be recorded, such as cleaning or aligning spray jets. All records shall be kept on file at least two years for regulatory inspection. Each washer shall be equipped with an indicating thermometer.~~

~~E. SINGLE-SERVICE CONTAINERS.~~

~~1. Single-service containers shall be manufactured from food-grade materials that do not impart odors or tastes to the product nor contaminate the product with microorganisms, toxic or injurious substances.~~

~~2. Single-service containers shall be packaged and stored in a manner approved by the Department prior to filling.~~

~~3. Unless otherwise approved by the Department, all single-service containers shall be inverted and rinsed with potable water, treated by filtered compressed air or vacuumed to remove dust prior to filling.~~

~~F. INSPECTION OF RETURNABLE CONTAINERS.~~

~~1. BOTTLES~~

~~(a) All empty bottles shall be visually inspected immediately after the final rinse of the washing operation for defects, chips, foreign objects, and unclean product contact surfaces as the bottles pass on a conveyor before a well-illuminated background at a speed slow enough for the inspector to achieve high efficiency. Bottles used exclusively for bottled water coolers do not have to pass before a well-illuminated background, but should be visually inspected prior to reuse.~~

~~(b) Dirty bottles shall be removed from the production line and either destroyed or rewashed. Defective bottles shall be removed from the production line and destroyed. When inspectors break bottles for cullet, adequate protection shall be provided for exposed bottles in the immediate are to prevent glass fragments from entering them.~~

~~(c) Electronic inspection devices can be used in addition to visual inspection; however, electronic inspection devices shall not be substituted for visual inspection of returnable bottles without the approval of the Department. Inspectors shall have good eyesight, with or without corrective lenses, and shall be rotated to noninspection work as often as is necessary to maintain high efficiency.~~

~~(d) Returnable bottles shall not be used where their condition or design may prevent proper inspection of the contents thereof.~~

~~2. METAL CANISTERS~~

~~(a) All metal canisters shall be visually inspected immediately after the final rinse of the washing operation for the presence of foreign objects or unclean product contact surfaces.~~

~~(b) Unclean canisters shall be either immediately returned to the washer or removed to the storage area for unclean canisters.~~

~~G. CONTAINER CLOSURES.~~

~~1. Container closures shall be manufactured from food-grade materials which do not impart odors or tastes to the product nor contaminate the product with microorganisms, toxic or injurious substances.~~

~~2. Container closures shall be received by the bottling plant in an undamaged package sealed by the manufacturer.~~

~~3. All container closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination. Closures which have been touched on the inner side by the operator, as may occur while adjusting equipment, shall be discarded.~~

~~4. Container closures not used during the period of processing operations shall be resealed in their original container or stored in an approved tightly covered container.~~

~~5. Only new container closures shall be used.~~

~~H. FILLING AND SEALING.~~

~~1. Containers shall be filled and sealed with approved mechanical equipment. Manual filling and sealing shall be prohibited, except when otherwise approved by the Department for package sizes in which mechanical sealing equipment is not yet readily available.~~

~~2. Filling equipment which fills glass containers under pressure should be provided with an adequate shield to protect against broken glass entering unsealed containers. Whenever a glass bottle breaks while being filled or sealed, the machinery involved shall be stopped and all broken glass shall be removed from parts which touch the opening of bottles or which contact the product. This shall be performed in such a manner to protect against transferring broken glass into nearby bottles which have exposed openings.~~

~~3. No person or his clothing shall come in contact with any portion of the container or equipment which might result in contamination of the product.~~

~~4. The contents of all imperfectly sealed containers shall be discarded.~~

~~I. INGREDIENTS AND LABELING.~~

~~1. All soft drinks and bottled waters shall be prepared with approved ingredients that meet all applicable ingredient regulations as defined by the United States Food and Drug Administration.~~

~~2. All soft drink and bottled water labeling shall conform to applicable federal and state labeling laws.~~

~~SECTION VIII. EXAMINATION AND CONDEMNATION OF UNWHOLESOME OR CONTAMINATED RAW MATERIALS OR FINISHED PRODUCT.~~

~~A. Samples of ingredients, drinks, and other substances shall be taken and examined by the Department as often as may be necessary for the detection of unwholesomeness or adulteration.~~

~~B. The Department may condemn and forbid the sale of, or cause to be removed and destroyed, any ingredients or products which are unwholesome or adulterated.~~

~~SECTION IX. ENFORCEMENT PROCEDURES~~

~~A. PERMITS~~

~~It shall be unlawful for any person to manufacture soft drinks or bottled waters in South Carolina without a valid permit issued by the Department for the specific bottling plant. Permits are not transferable.~~

~~B. ISSUANCE OF PERMITS~~

~~1. Any person desiring to manufacture soft drinks or bottled waters in South Carolina shall make written application for a permit on the appropriate application form provided by the Department. This form shall include name and address of bottling plant's owner, location and type of facility and products to be manufactured, applicant's signature and such other information deemed necessary by the Department to determine compliance with this regulation.~~

~~2. A permit is valid as long as the bottling plant continues in operation under the same ownership or until the permit is revoked or suspended.~~

~~3. Any person whose application for a permit is denied under this regulation may request that a hearing be held as required by law.~~

~~C. SUSPENSION OF PERMIT~~

~~1. Permits may be suspended temporarily by the Department for repeated violation, for total number of violations, or for interference with the Department in the performance of its duty. Prior to permit suspension, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be suspended and that the permit shall be suspended at the end of the 15 days following service of such notice unless a written request for a hearing is filed with the Department by the permit holder within such 15-day period. If no written request is filed within 15 days, the permit is suspended and bottling operations shall immediately cease. If the hearing upholds the finds of the Department, the permit shall be suspended until the reasons for the suspension have been corrected.~~

~~2. The Department may without warning, notice, or hearing suspend the permit to operate a bottling plant when it is determined that the operation of the bottling plant constitutes an imminent hazard to public health. Following immediate permit suspension, all bottling operations shall immediately cease. The Department shall promptly notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit was suspended, and that an opportunity for a hearing will be provided if a written request for a hearing is filed with the Department by the permit holder within 15 days. If no written request for a hearing is filed within 15 days, the suspension is sustained. During the hearing process, the permit shall remain suspended unless the imminent health hazard has been corrected.~~

~~3. Hearings on suspension of permits as provided for in this regulation shall be conducted in accordance, where applicable, with the South Carolina Administrative Procedures Act, Sections 1-23-310 et seq., 1976 Code of Laws of South Carolina as amended, and applicable regulations.~~

~~D. REVOCATION OF PERMIT.~~

~~1. The permit may be revoked for failure to correct deficiencies within prescribed time limits or for repeated violations of any of the requirements of this regulation, or for the interference with the health authority in the performance of duty.~~

~~2. Prior to revocation, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be revoked and that the permit shall be revoked at the end of the 15 days following service of such notice unless a written request is filed with the Department by the permit holder within such 15-day period.~~

~~3. Any person whose permit is revoked shall not be eligible to apply for repermitting within one year from the date of revocation. Any person whose permit has previously been revoked and who obtains a subsequent permit and violates the provisions of this regulation, resulting in revocation of the bottling plants permit for the second time, shall not be granted another permit.~~

~~4. Hearings on revocation of permits as provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, SC Code Ann. 1-23-310 et seq. (1976, as amended) and applicable regulations.~~

~~E. SERVICE OF NOTICES~~

~~A notice provided for in this regulation is properly served when it is delivered to the permit holder, manager or other duly authorized representative, or when it is sent by registered or certified mail, return receipt requested and delivery restricted to the addressee, to the last known address of the bottling plant's permit holder.~~

~~F. HEARINGS~~

~~All hearings provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, SC Code Ann. 1-23-310 et seq. (1976, as amended) and applicable regulations.~~

~~G. INSPECTIONS~~

~~Inspections of bottling plants shall be performed as frequently as deemed necessary to insure compliance with this regulation.~~

~~H. ACCESS~~

~~Representatives of the Department, after proper identification, shall be permitted to enter any bottling plant at any reasonable time for the purpose of making inspections to determine compliance with this regulation. The representatives shall be permitted to examine the records of the establishment to ascertain information relative to the purchasing, receiving, and use of such food products or other supplies used in the manufacturing of soft drinks and bottled waters. It shall be unlawful for any representatives of the Department who, in an official capacity, obtain any information under the provisions of this regulation which is entitled to protection as a trade secret (including information as to quantity, quality, source or disposition of soft drinks or bottled water products, or results of inspections or tests thereof) to use such information to their own advantage or to reveal it to any unauthorized person.~~

~~I. REPORT OF INSPECTIONS~~

~~When an inspection of a bottling plant is conducted, a copy of the completed inspection report form shall be furnished to the permit holder, manager or other duly authorized representative.~~

~~J. SUBMISSION OF PLANS~~

~~When a bottling plant is constructed or extensively remodeled and when an existing structure is converted for use as a bottling plant, properly prepared plans and specifications for such construction, remodeling, or conversion should be submitted to the Department for review and approval before construction, remodeling, or conversion. The plans and specifications should indicate the proposed layout, arrangement, mechanical plans, and construction materials of work areas, and the make and model number of proposed fixed equipment and facilities. The Department shall approve the plans and specifications if they meet the requirements of this regulation. In the absence of plan approval, issuance of the bottling plant permit shall be determined by compliance with all applicable requirements of this regulation.~~

~~K. RECIPROCITY~~

~~Upon receiving from any person, entity, or any regulatory agency outside this state, a report of a possible violation of this regulation by a permit holder, the Department may conduct such inspection or investigation as it deems appropriate. Upon receiving information that soft drinks or bottled waters manufactured or bottled outside this state and introduced into this state may have been manufactured in violation of applicable state or federal law or not in conformance with prevailing and applicable standards and good public health practices, the Department may notify appropriate regulatory authorities located outside this state and request that such authorities take appropriate action.~~

~~L. OUT-OF-STATE IMPORTS~~

~~Due to additional FDA laboratory testing requirements for bottled water products, out-of-state water bottlers should submit the following to the Department: (a) a certification signed by the applicable regulatory agency with jurisdiction over the bottling in the state of origin stating that the plant(s) is permitted or licensed as required, the source water supply meets all EPA public drinking water requirements, and is operated and maintained in a sanitary manner based on previous plant inspection(s); (b) the name, address, and phone number(s) of all plant(s) manufacturing bottled products for sale in South Carolina; (c) a copy of the latest finished bottled water product water analyses (total coliform, inorganic, organic, radiological); and (d) the location(s) where the product(s) may be sampled in South Carolina.~~

~~M. OUT-OF-COUNTRY IMPORTS~~

~~For bottled water products imported from outside the United States, permission should be obtained from the Department prior to initiating the importation of bottled water products into South Carolina. This should include a certification signed by the applicable regulatory agency in the country of origin with jurisdiction over the bottling that (a) describes the requirements of said country for the source, bottling facility, treatment, bottling practices, and finished products; (b) states the date of the last officially authorized inspection by the applicable regulatory agency or acceptable third-party inspection organization and review of said source, facility, treatment, bottling practices, and final products; (c) certifies that said source, facility, treatment, bottling practices, and finished products meet the standards of the country of origin except those that are in conflict with U.S. State and Federal laws and regulations; and (d) where the product(s) may be sampled in South Carolina.~~

~~N. RECALL~~

~~Each bottling plant operator shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the operator or the Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the Department determines, based upon representative samples, risk analysis, information provided by the bottling supplier, and other information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the bottling supplier to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The bottling supplier shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.~~

~~O. ENFORCEMENT PROVISIONS~~

~~This regulation is issued under the authority of South Carolina Code Ann. Section 44-1-140 (1976, as amended) and shall be enforced by the Department.~~

~~P. PENALTIES~~

~~Violation of this regulation shall be punishable in accordance with South Carolina Code Ann. Section 44-1-150 (1976, as amended).~~

61-32. Wholesale Bottled Water, Soft Drink, and Ice Manufacturing

Statutory Authority: S.C. Code Sections 44-1-140 and 44-1-150

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SECTION I. PURPOSE

This regulation sets forth minimum health standards, procedures, and practices to ensure that wholesale BOTTLED WATER, SOFT DRINKS, and ICE are manufactured in South Carolina in a safe and wholesome manner.

SECTION II. SCOPE

This regulation shall apply to all PERSONS who manufacture or distribute wholesale BOTTLED WATER, SOFT DRINKS, or ICE, sold for human consumption in South Carolina.

SECTION III. DEFINITIONS

A. ADEQUATE - substantial compliance with acceptable health standards, procedures, and practices.

B. ADULTERATED or ADULTERATION - BOTTLED WATER, SOFT DRINKS, or ICE are deemed to be ADULTERATED if the product:

1. Bears or contains any poisonous or deleterious substance in a quantity that may render it injurious to health;

2. Bears or contains any added poisonous or deleterious substance for which no state or federal regulation has established a safe tolerance, or in excess of such tolerance if one has been established;

3. Consists, in whole or in part, of any substance unfit for human consumption;

4. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;

5. Is packaged in a container which is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

6. Has any substance added thereto, or mixed or packaged therewith, so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

7. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. Section 342).

C. APPROVED - acceptable to the Department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

D. APPROVED LABORATORY - a laboratory APPROVED by the Department or certified by the U.S. Environmental Protection Agency (EPA), or certified (accredited) by a third-party organization acceptable to the Department.

E. APPROVED SOURCE - the source of the water used in a plant's operations or a bottled water plant's product water, whether it be from a spring, artesian well, drilled well, public or community water system, or any other source that has been inspected and the water sampled, analyzed, and found of a safe and sanitary quality with or without treatment, and APPROVED by the Department in accordance with Regulation 61-58, State Primary Drinking Water Regulations.

F. ARTESIAN WATER - BOTTLED WATER from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer. ARTESIAN WATER may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to the Department that the water level stands at some height above the top of the aquifer.

G. BOTTLED WATER - water that is intended for human consumption and that is sealed in bottles or other CONTAINERS with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. It does not include those food ingredients that are declared in ingredient labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," "SPARKLING WATER," and "tonic water."

H. BOTTLING - filling, capping, packaging, or enclosing in CONTAINERS.

I. BOTTLING PLANT - any establishment involved in the manufacturing or packaging of SOFT DRINKS and/or BOTTLED WATERS.

J. BUSINESS DAY - every official work day of the week excluding weekends and state holidays.

K. BULK WATER - source water collected at an APPROVED site remote from the BOTTLING PLANT and transported to the BOTTLING PLANT for further processing and BOTTLING.

L. CODE OF FEDERAL REGULATION (CFR) - a codification of the general and permanent rules and regulations (administrative LAW) published in the Federal Register by the executive departments and agencies of the federal government of the United States. Citations to the CFR in this regulation refer sequentially to the Title, Part, and Section numbers. For example, the citation 21 CFR 117.10 refers to Title 21, Part 117, Section 117.10.

M. CONTAINER - any material used for the packaging of SOFT DRINKS, BOTTLED WATERS, and ICE, whether of glass, plastic, metal, paper, or any combination thereof.

N. DEMINERALIZED WATER - BOTTLED WATER that is produced by distillation, deionization, reverse osmosis, or other suitable process, that meets the definition of PURIFIED WATER in the United

States Pharmacopoeia, and is specified by the U. S. Food and Drug Administration (FDA) in 21 CFR 165.110.

O. DEIONIZED WATER - BOTTLED WATER that has been produced by a process of deionization, that meets the definition of "PURIFIED WATER" in the United States Pharmacopoeia, and is specified by the FDA in 21 CFR 165.110.

P. DEPARTMENT - the South Carolina Department of Health and Environmental Control and its authorized representatives.

Q. DISTILLED WATER - BOTTLED WATER that has been produced by a process of distillation, meets the definition of "PURIFIED WATER" in the United States Pharmacopoeia, and is specified by FDA in 21 CFR Section 165.110.

R. DRINKING WATER - water that is intended for human consumption and that is sealed in bottles or other CONTAINERS with no added ingredients, except that it may optionally contain safe and suitable antimicrobial agents.

S. EMPLOYEE - a permit holder, PERSON in charge, PERSON having supervisory or managerial duties, PERSON on the payroll, family member, volunteer, PERSON performing work under a contractual agreement, or any other PERSON working in a BOTTLED WATER, SOFT DRINK, or ICE plant or distribution station.

T. EQUIPMENT - all machinery, utensils, conveyors, CONTAINERS, cases, and other articles used in the manufacturing of BOTTLED WATER, SOFT DRINKS, or ICE.

U. EXCLUSION - prevention of a PERSON from working as an EMPLOYEE in a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station, or entering a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station as an EMPLOYEE.

V. FDA - United States Food and Drug Administration.

W. FOOD - means FOOD as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act ("FD&C") and includes raw materials and ingredients.

X. GROUND WATER - water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. GROUND WATER must not be under the direct influence of surface water.

Y. ICE - the product, in any form, obtained as a result of freezing water by mechanical or artificial means.

Z. ICE VENDING MACHINES - any self-service machines that act as stand-alone units and may operate without full-time service personnel. These units are activated by the insertion of money; the ICE is bagged automatically or dispensed in bulk to the customer.

AA. IMMINENT HEALTH HAZARD - a significant threat or danger to health that is considered to exist when there is sufficient evidence to show that a product, practice, circumstance, or event creates a situation requiring immediate correction or cessation of operation to prevent illness or injury based on the number of potential illnesses or injuries, and the nature, severity, and duration of the anticipated illness or injury.

BB. LAW - applicable local, state, and federal statues, regulations, and ordinances.

CC. MANUFACTURED BOTTLED WATER, SOFT DRINKS, AND/OR ICE PRODUCTS DISTRIBUTION STATION - any place or PREMISES, except retailers, where manufactured BOTTLED WATER, SOFT DRINKS, and ICE products are received, stored, and dispensed to retailers (may also be referred to as “Distribution Station”).

DD. MANUFACTURED BOTTLED WATER, SOFT DRINKS, AND/OR ICE PRODUCTS DISTRIBUTOR - any PERSON, except a retailer, who receives, stores, and dispenses manufactured BOTTLED WATER, SOFT DRINKS, and ICE products to retailers (may also be referred to as “Distributor”).

EE. MANUFACTURED BOTTLED WATER, SOFT DRINKS, AND/OR ICE PRODUCTS MANUFACTURER - any PERSON, except a retailer, who manufactures, processes, or freezes manufactured BOTTLED WATER, SOFT DRINKS, and ICE products for distribution or sale.

FF. MANUFACTURED BOTTLED WATER, SOFT DRINKS, AND/OR ICE PRODUCTS PLANT - any place or PREMISES, except retailers, where manufactured BOTTLED WATER, SOFT DRINKS, and ICE products are manufactured, processed, or frozen for distribution or sale.

GG. MICROORGANISMS - means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are PATHOGENS. The term "undesirable MICROORGANISMS" includes those MICROORGANISMS that are PATHOGENS, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be ADULTERATED.

HH. MINERAL WATER - BOTTLED WATER containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more boreholes or springs, originating from a geologically and physically protected underground water source. MINERAL WATER is distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, with consideration given to the cycles of natural fluctuations. No minerals may be added to this water.

II. NATURAL WATER - bottled spring, mineral, artesian, or WELL WATER that is derived from an underground formation or water from surface water that only requires minimal processing, is not derived from a municipal system or public water supply, and is unmodified except for limited treatment (e.g., filtration, ozonation, or equivalent disinfection process).

JJ. PACKAGED ICE - ICE products packaged by APPROVED manufacturers and sold through retail outlets.

KK. PATHOGEN - a microorganism of public health significance.

LL. PERMIT - the document issued by the DEPARTMENT that authorizes a PERSON or entity to operate a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station.

MM. PERMIT HOLDER - the entity, such as the owner, the owner’s agent, or other PERSON, that possesses a valid PERMIT to operate a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station and is legally responsible for its operation.

NN. PERSON - an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

OO. PEST - any objectionable animals or insects including, but not limited to, birds, rodents, flies and larvae.

PP. PURIFIED WATER - BOTTLED WATER produced by distillation, deionization, reverse osmosis, or other suitable process, that meets the definition of PURIFIED WATER in the United States Pharmacopoeia, and is specified by the FDA in 21 CFR 165.110.

QQ. PREMISES –

1. The physical facility, its contents, its land, and any adjacent or bordering contiguous land or property under the control of the PERMIT HOLDER; or

2. The physical facility, its contents, and land or property not described in (a) of this definition if the facilities and contents are under the control of the PERMIT HOLDER and may impact the BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station personnel, facilities, or operations, and the BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station is only one component of a larger operation, such as a healthcare facility, hotel, motel, school, recreational camp, or prison.

RR. RESTRICTION - limitation of the activities of an EMPLOYEE so that there is no risk of transmitting a disease that is transmissible through BOTTLED WATER, SOFT DRINKS, or ICE or their ingredients and the EMPLOYEE does not work with exposed BOTTLED WATER, SOFT DRINKS, or ICE or their ingredients, clean EQUIPMENT, utensils, linens, or unwrapped single-service or single-use articles.

SS. RETAIL FOOD ESTABLISHMENT - an establishment that sells FOOD products directly to consumers as its primary function. RETAIL FOOD ESTABLISHMENTS include, but are not limited to, grocery stores, convenience stores, roadside stands, farmers markets, and community supported agriculture (CSA) operations. Any business making FOOD (including a farm business) with at least 50.1 percent in direct to individual consumer FOOD sales satisfies the definition of a RETAIL FOOD ESTABLISHMENT and is exempt from the Bioterrorism Act registration regulations under the 2002 Bioterrorism Act (21 CFR 1.225) as a RETAIL FOOD ESTABLISHMENT. The term “consumers” does not include businesses. A RETAIL FOOD ESTABLISHMENT also includes certain farm-operated businesses selling FOOD directly to consumers as their primary function.

TT. RETAILER - any PERSON who sells, serves, or dispenses at retail manufactured BOTTLED WATER, SOFT DRINKS, or ICE products that have been processed in an APPROVED manufactured BOTTLED WATER, SOFT DRINKS, or ICE products plant.

UU. REMODELED - any enlarging, replacing of floors, walls, or ceilings, or changing in any respect the structure at which a SOFT DRINK, BOTTLED WATER, or ICE plant is housed. This does not apply to repainting or refinishing of floors or walls.

VV. REVERSE OSMOSIS WATER - BOTTLED WATER that is produced by a process of reverse osmosis, that meets the definition of “PURIFIED WATER” in the United States Pharmacopoeia, and is specified by the FDA in 21 CFR 165.110.

WW. RISK - the likelihood that an adverse health effect will occur within a population as a result of a hazard in a FOOD.

XX. SANITIZE - to adequately treat cleaned surfaces by a DEPARTMENT -accepted process that is effective in destroying vegetative cells of PATHOGENS, and in substantially reducing numbers of other

undesirable MICROORGANISMS, but without adversely affecting the product or its safety for the consumer.

YY. SOFT DRINK - any nonalcoholic, flavored carbonated beverage, including but not limited to soda or soda water, fruit flavored drink, nonalcoholic still beverage, and seltzer or club soda.

ZZ. SPARKLING BOTTLED WATER - BOTTLED WATER that, after treatment and possible replacement of carbon dioxide, contains the same amount of carbon dioxide that it had at the emergence from the source. Manufacturers may add carbonation to previously noncarbonated BOTTLED WATER products and label such water appropriately (e.g. sparkling SPRING WATER).

AAA. SPRING WATER - BOTTLED WATER derived from an underground formation from which water flows naturally to the surface of the earth. SPRING WATER must comply with the FDA standard of identity in 21 CFR 165.110.

BBB. STERILE WATER - BOTTLED WATER that meets the requirements under "Sterility Tests" <71> in the current United States Pharmacopoeia and specified by the FDA in 21 CFR 165.110.

CCC. UNEXPOSED PACKAGED FOOD - packaged FOOD that is not exposed to the environment.

DDD. WELL WATER - BOTTLED WATER from a hole bored, drilled, or otherwise constructed in the ground that taps the water of an aquifer.

Additional definitions related to this regulation are found in 21 CFR 117.3, as amended.

SECTION IV. ADULTERATED OR MISBRANDED BOTTLED WATER, SOFT DRINKS, OR ICE

A. No PERSON within South Carolina, or its jurisdiction, shall produce, provide, sell, offer, or expose for sale or have in possession with intent to sell, any BOTTLED WATER, SOFT DRINKS, or ICE that is ADULTERATED or misbranded. Any BOTTLED WATER, SOFT DRINK, or ICE that may contain any unwholesome substance, or that does not conform to an applicable standard of identity or other requirement specified under Section III for that particular BOTTLED WATER, SOFT DRINK, or ICE product, shall be deemed ADULTERATED and/or misbranded.

B. The DEPARTMENT may place a hold order on any BOTTLED WATER, SOFT DRINKS, or ICE it determines or has reason to believe:

1. originated from an unapproved SOURCE;

2. may be unsafe, unwholesome, ADULTERATED, misbranded, or not honestly presented;

3. is not labeled according to LAW; or

4. is otherwise not in compliance with this regulation.

C. The DEPARTMENT may suspend a PERSON'S PERMIT for violating a hold order.

D. The DEPARTMENT may impound, condemn, forbid the sale of, or cause to be removed or destroyed, any FOOD that is determined to be in violation of this regulation, unwholesome, contaminated, ADULTERATED, misbranded, or from an unapproved source.

E. The DEPARTMENT may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the FOOD, as specified above, without prior warning, notice of a hearing, or a hearing on the hold order.

F. The DEPARTMENT may examine BOTTLED WATER, SOFT DRINKS, and ICE as often as necessary to determine freedom from ADULTERATION or misbranding. Under a hold order, BOTTLED WATER, SOFT DRINKS, or ICE shall be suitably stored. No PERSON shall remove or alter a hold order, notice, or tag placed on BOTTLED WATER, SOFT DRINKS, or ICE by the DEPARTMENT. No PERSON shall relabel, repack, reprocess, alter, dispose of, or destroy such BOTTLED WATER, SOFT DRINKS, or ICE, or the CONTAINERS thereof, without permission of the DEPARTMENT, except on order by a court of competent jurisdiction.

G. When BOTTLED WATER, SOFT DRINKS or ICE are found to be ADULTERATED by pesticides, herbicides, or other poisonous substances, the PERSON or entity in possession of the product shall remove the product from the market, disposed of, and sale stopped until analysis provides the product to be free from ADULTERATION.

SECTION V. COMPLIANCE PROCEDURES

A. PERMIT.

1. It shall be unlawful for any PERSON to manufacture or distribute BOTTLED WATER, SOFT DRINKS, and/or ICE products in South Carolina without a valid PERMIT issued by the DEPARTMENT for the specific BOTTLED WATER, SOFT DRINK, or ICE products plant or distribution station. Grocery stores, restaurants, soda fountains, and similar establishments where BOTTLED WATER, SOFT DRINKS, or ICE are served or sold at retail, but not processed, may be exempt from the requirements of this section.

2. Every BOTTLED WATER, SOFT DRINKS, or ICE manufacturer and distributor must obtain and maintain a PERMIT. PERMITS are nontransferable with respect to PERSONS and/or locations.

B. Suspension of PERMIT.

1. The DEPARTMENT may suspend a PERMIT whenever:

a. it has reason to believe a public health hazard exists;

b. the PERMIT HOLDER has violated any of the requirements of this regulation;

c. the PERMIT HOLDER has violated its PERMIT or an order of the DEPARTMENT, including but not limited to a hold order; or

d. the PERMIT HOLDER has interfered with the DEPARTMENT in the performance of its duties.

A suspension shall remain in effect until the violation has been corrected to the satisfaction of the DEPARTMENT.

2. The DEPARTMENT may without prior warning, notice of a hearing, or hearing suspend a PERMIT to operate a BOTTLED WATER, SOFT DRINKS, or ICE plant or distribution station when the DEPARTMENT determines that the operation of the BOTTLED WATER, SOFT DRINK, or ICE plant or distribution station, including but not limited to a willful refusal to permit authorized inspection, constitutes

an IMMINENT HEALTH HAZARD. Upon summary PERMIT suspension, all manufacturing and distribution operations shall immediately cease. During the process, the PERMIT shall remain suspended unless the IMMINENT HEALTH HAZARD has been corrected.

3. Any BOTTLED WATER, SOFT DRINK, or ICE manufacturer or distributor whose PERMIT has been suspended may make written application for the reinstatement of the PERMIT.

4. Within seven (7) business days of receiving the written application, the DEPARTMENT shall make inspections and/or collect samples for analysis to determine whether the conditions cited in the notice of suspension no longer exist. If conditions warrant, the DEPARTMENT may reinstate the PERMIT.

C. Revocation of PERMIT.

1. The DEPARTMENT may revoke a PERMIT for repeated violations of any of the requirements of this regulation, the PERMIT, or an order of the DEPARTMENT, or for interference with the DEPARTMENT or its staff in the performance of duties. Notwithstanding any other provisions of this regulation, the PERMIT may be revoked if the DEPARTMENT is threatened with bodily harm or physical interference in the performance of inspectional duties.

2. The DEPARTMENT may deny a new PERMIT based upon past noncompliance, including previous enforcement, suspension, or revocation history.

3. Any PERSON whose PERMIT is revoked shall not be eligible to apply for re-permitting within one (1) year from the date of revocation. Any PERSON whose PERMIT has previously been revoked and who obtains a subsequent PERMIT and violates the provisions of this regulation, resulting in revocation of the PERMIT for a second time, shall not be granted another PERMIT for a period of five (5) years.

SECTION VI. LABELING

All BOTTLED WATER, SOFT DRINK, and ICE products shall be labeled according to the requirements in 21 CFR Part 101, as amended.

SECTION VII. INSPECTION OF BOTTLED WATER, SOFT DRINK, AND ICE PLANTS AND DISTRIBUTION STATIONS

A. Each BOTTLED WATER, SOFT DRINK, or ICE manufacturer and distributor whose products are intended for consumption within South Carolina shall be inspected by the DEPARTMENT prior to the issuance of a PERMIT.

B. Following the issuance of a PERMIT, the DEPARTMENT shall inspect each BOTTLED WATER, SOFT DRINK, or ICE manufacturer and distributor at a frequency determined by the RISK level assigned to the product(s) being manufactured or distributed or as otherwise deemed necessary by the DEPARTMENT to determine compliance with this regulation.

C. A copy of the inspection report will be provided, either electronically or in paper form, to the PERMIT holder, manager, or other duly authorized representative.

D. Every BOTTLED WATER, SOFT DRINK, or ICE manufacturer and distributor shall, upon request of a DEPARTMENT representative, permit DEPARTMENT access to all parts of the establishment or facilities to determine compliance with the provisions of this regulation. A PERMIT HOLDER, manager, or other duly authorized representative shall furnish the DEPARTMENT, upon request and for official use

only, a true statement of the actual quantities of BOTTLED WATER, SOFT DRINK, or ICE product purchased and sold, a list of all sources of such BOTTLED WATER, SOFT DRINK, or ICE products, records of inspections, and records of tests.

E. It is unlawful for any PERSON who, in an official capacity, obtains any information under the provisions of this regulation which is entitled to protection as a trade secret to use such information to his own advantage or to reveal it to any unauthorized PERSON.

SECTION VIII. EXAMINATION OF BOTTLED WATER, SOFT DRINKS, AND ICE

A. Chemical, microbiological, or extraneous material testing procedures shall be used, where necessary, to identify sanitation failures or possible contamination. All FOOD that has become ADULTERATED shall be rejected, or if permissible, treated or processed to eliminate the contamination.

B. BOTTLED WATER manufacturers must perform weekly total coliform monitoring on the finished product of each BOTTLED WATER product type and conduct quarterly rinse/swab tests on BOTTLED WATER CONTAINERS (incoming, as well as those immediately from the washer) and closures. This monitoring and testing must be performed in-house or by an APPROVED LABORATORY as stipulated in 21 CFR Section 129.80. For microbiological contaminants (total coliform), each BOTTLED WATER manufacturer must analyze a representative sample from a batch or segment of a continuous production run for each BOTTLED WATER product type produced by the plant.

C. Samples of source water shall be taken and analyzed by the BOTTLED WATER plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every four (4) years for radiological contaminants. Facilities that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of the Environmental Protection Agency's National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants.

D. For chemical, physical, and radiological contaminants, a representative sample from a batch or segment of continuous production run for each type of finished BOTTLED WATER product produced by a water BOTTLING PLANT shall be analyzed annually to ensure that the product(s) complies with current FDA standards.

SECTION IX. BOTTLED WATER, SOFT DRINK, AND ICE PLANTS AND DISTRIBUTION STATIONS

A. Water supply for BOTTLED WATER, SOFT DRINK, and ICE plants and ICE and water vending.

1. The water supply shall be from an APPROVED public water system as defined in R.61-58, State Primary Drinking Water Regulations.

2. The design, operation, and maintenance of water purification systems used to further treat potable water shall be certified as meeting the specifications of the American National Standard Institute/National Sanitation Foundation (ANSI/NSF). All chemicals and products added to the potable water shall meet ANSI/NSF Standard 60. All materials and products installed that come into contact with the potable water shall meet ANSI/NSF Standard 61. The certifying party shall be accredited by the American National Standards Institute. They shall not be operated beyond their rated capacity and shall be maintained in a clean, sanitary condition at all times. This shall include dispensed water and ICE vending machines.

3. Potable running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of SOFT DRINKS, BOTTLED WATER, and ICE; for the cleaning of EQUIPMENT, utensils, and CONTAINERS; and for EMPLOYEE sanitary facilities.

4. Carbonated water shall be conveyed in APPROVED stainless steel or equal FOOD-grade piping and not in piping of galvanized iron, lead, zinc, or other deleterious materials.

5. All water storage and cooling tanks shall be of noncorrosive material, properly covered; air vents properly filtered, clean, and free from dust both inside and outside; and the inlet and outlet so arranged as to prevent contamination during filling and emptying.

B. Required rooms.

1. Except as APPROVED by the DEPARTMENT under paragraph B.2 below, each BOTTLED WATER and SOFT DRINK plant shall have a separate room (commonly called a syrup or blend room) or separate area of the filling room for mixing ingredients for BOTTLED WATER or SOFT DRINKS. This room or separate area of the filling room shall be used only for mixing ingredients and storage of mixed batches.

2. Each BOTTLED WATER and SOFT DRINK plant shall have a separate room for filling and sealing CONTAINERS (commonly called a filling or BOTTLING room). This room shall contain only necessary filling, sealing, electronic inspection, coding, and labeling EQUIPMENT. Only the exit end of the bottle washing machine shall open into this room through a tight-fitting wall. If APPROVED by the DEPARTMENT, the mixing of ingredients and storage of mixed batches may be conducted in this room.

3. ICE for human consumption shall be processed and packaged only in rooms used exclusively for processing and packaging ICE for human consumption. ICE for human consumption shall not be processed or packaged on open platforms or on trucks or delivery vehicles, or in any manner which would permit contamination from overhead drip, condensation, dirt, or other contaminants.

C. Transportation of BULK WATER for BOTTLED WATER plants.

1. BULK WATER shall be from a public water system as APPROVED and defined in R.61-58 by the DEPARTMENT.

2. The means and methods of transporting BULK WATER shall be APPROVED by the DEPARTMENT. Bulk tanks, hoses, pumps, and connections used for loading, transporting, and unloading water shall be SANITIZED. Source water for transport shall be treated with an effective disinfectant APPROVED by the DEPARTMENT at an APPROVED concentration prior to being transported.

3. Tank filling and delivery hose connections shall be cleaned and SANITIZED on a regular basis. The tank shall be sealed at all times except when being filled, being cleaned and SANITIZED, and when the water is being unloaded. A record of such cleaning and sanitizing shall be maintained with the vehicle and shall be available upon request by the DEPARTMENT. Pumps, hoses, connections, and fittings shall be capped and protected from contamination when not in use. The tank manhole shall not be used as a means of filling the tank. To prevent collapse of the tank during delivery of BULK WATER, the manhole may be opened but shall be provided with an air filter to prevent contamination.

4. All surfaces which come into contact with water during storage prior to transport shall be of smooth, impervious, nonabsorbent, corrosion resistant, and nontoxic material such as stainless steel of the American Iron and Steel Institute 300 Series, or equally corrosion resistant, nontoxic material. All water contact

surfaces shall be free of substances that may render the water hazardous to health or may adversely affect the flavor, color, turbidity, odor, radiological, microbiological, or chemical quality of the water.

5. BULK WATER transport is intended to move source water from one area to another for the purpose of treatment, packaging, and human consumption. Such water shall not be dispensed directly to consumers from a BULK WATER transport tank or indirectly through some other vending device, unless otherwise APPROVED by the DEPARTMENT. In case of an emergency, such as a DRINKING WATER shortage or outage, or a contaminated water supply, treated water may be dispensed directly from a properly SANITIZED water transport tank.

D. Returnable CONTAINER cleaning.

1. All returnable CONTAINERS shall be adequately, mechanically washed and SANITIZED prior to filling. Unless the CONTAINERS are sealed after washing, they shall be washed immediately prior to filling. Hand cleaning of CONTAINERS is prohibited except as a preliminary to subsequent mechanical washing.

2. Metal and glass CONTAINERS.

(a) All metal and glass CONTAINERS shall be exposed to a minimum three percent (3%) alkali solution of which not less than sixty percent (60%) is caustic soda (sodium hydroxide) by an APPROVED automatic mechanical method for a period of not less than five (5) minutes at a temperature of not less than 130ºF, or to an equivalent cleaning and sanitizing process APPROVED by the DEPARTMENT.

(b) CONTAINERS shall be rinsed of all caustic soda with potable water.

3. Polycarbonate CONTAINERS.

(a) Polycarbonate CONTAINERS shall be cleaned with APPROVED non-caustic detergents at their required concentrations by an APPROVED mechanical method.

(b) An APPROVED sanitizing rinse consisting of chlorine, bromine, iodine, quaternary ammonia, or ozonated water at the proper APPROVED temperature/time/concentration must follow the cleaning cycle.

4. A permanent record of key operating parameters of the container washer should be maintained. These records or logs should include, but are not limited to, wash temperatures, concentrations of cleaners, concentrations of sanitizers, lack of carryover of cleaners or caustic in bottles, and maintenance on the washer. Tests on cleaner/sanitizer concentrations and carryover should be carried out at start-up and regularly thereafter throughout the shift. All maintenance on the washer should be recorded, such as cleaning or aligning spray jets. All records shall be kept on file at least two (2) years for regulatory inspection. Each washer shall be equipped with an indicating thermometer.

E. Single-service CONTAINERS.

1. Single-service CONTAINERS shall be manufactured from FOOD-grade materials that do not impart odors or tastes to the product, nor contaminate the product with MICROORGANISMS, or toxic or injurious substances.

2. Single-service CONTAINERS shall be packaged and stored in a manner APPROVED by the DEPARTMENT prior to filling.

3. Unless otherwise APPROVED by the DEPARTMENT, all single-service CONTAINERS shall be inverted and rinsed with potable water, then treated by filtered compressed air or vacuumed to remove dust prior to filling.

F. Inspection of returnable CONTAINERS.

1. Bottles.

(a) All empty bottles shall be visually inspected immediately after the final rinse of the washing operation for defects, chips, foreign objects, and unclean product contact surfaces as the bottles pass on a conveyor before a well-illuminated background at a speed slow enough for the inspector to achieve high efficiency.

(b) Dirty bottles shall be removed from the production line and either destroyed or rewashed. Defective bottles shall be removed from the production line and destroyed. When inspectors break bottles for cullet, ADEQUATE protection shall be provided for exposed bottles in the immediate area to prevent glass fragments from entering them.

(c) Electronic inspection devices can be used in addition to visual inspection; however, electronic inspection devices shall not be substituted for visual inspection of returnable bottles without the approval of the DEPARTMENT. Inspectors shall have good eyesight, with or without corrective lenses, and shall be rotated to non-inspection work as often as is necessary to maintain high efficiency.

(d) Returnable bottles shall not be used where their condition or design may prevent proper inspection of the contents thereof.

2. Metal canisters.

(a) All metal canisters shall be visually inspected immediately after the final rinse of the washing operation for the presence of foreign objects or unclean product contact surfaces.

(b) Unclean canisters shall be either immediately returned to the washer or removed to the storage area for unclean canisters.

G. Container closures.

1. Container closures shall be manufactured from FOOD-grade materials which do not impart odors or tastes to the product, nor contaminate the product with MICROORGANISMS, or toxic or injurious substances.

2. Container closures shall be received by the BOTTLING PLANT in an undamaged package sealed by the manufacturer.

3. All container closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination. Closures which have been touched on the inner side by the operator, as may occur while adjusting EQUIPMENT, shall be discarded.

4. Container closures not used during the period of processing operations shall be resealed in their original container or stored in an APPROVED tightly covered container.

5. Only new container closures shall be used.

H. Filling and sealing.

1. CONTAINERS shall be filled and sealed with APPROVED mechanical EQUIPMENT. Manual filling and sealing shall be prohibited, except when otherwise APPROVED by the DEPARTMENT for package sizes in which mechanical sealing EQUIPMENT is not yet readily available.

2. Filling EQUIPMENT which fills glass CONTAINERS under pressure should be provided with an ADEQUATE shield to protect against broken glass entering unsealed CONTAINERS. Whenever a glass bottle breaks while being filled or sealed, the machinery involved shall be stopped and all broken glass shall be removed from parts that touch the opening of bottles or contact the product. This shall be performed in such a manner to protect against transferring broken glass into nearby bottles that have exposed openings.

3. No PERSON or his clothing shall come in contact with any portion of the container or EQUIPMENT that might result in contamination of the product.

4. The contents of all imperfectly sealed CONTAINERS shall be discarded.

I. SANITATION OF BOTTLED WATER, SOFT DRINK, AND ICE PLANTS AND DISTRIBUTION STATIONS

1. All BOTTLED WATER, SOFT DRINK, and ICE manufacturers and distributors, regardless of exemption status, shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, as amended.

2. All BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations that have been granted a Qualified Facility Exemption by the FDA or that are solely engaged in the storage of refrigerated UNEXPOSED PACKAGED FOODS when temperature controls are necessary to prevent PATHOGEN growth shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart D - Modified Requirements, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, and be familiar with Subpart E - Withdrawal of a Qualified Facility Exemption, as amended.

3. All BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations that have not been granted a Qualified Facility Exemption by the FDA shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart C - Hazard Analysis and RISK -Based Preventive Controls, and Subpart F- Requirements Applying to Records That Must Be Established and Maintained, as amended.

4. All BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations under an FDA order to withdraw their Qualified Facility Exemption are subject to the requirements of 21 CFR Part 117, Subpart E - Withdrawal of a Qualified Facility Exemption, as amended.

5. BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations that have not been granted a Qualified Facility Exemption by the FDA and have identified a hazard requiring a supply-chain applied control shall comply with the requirements of 21 CFR Part 117, Subpart G - Supply-Chain Program, as amended.

SECTION X. SUBMISSION OF PLANS

Before a SOFT DRINK, BOTTLED WATER, or ICE plant is constructed or extensively REMODELED, or when an existing structure is converted for use as a SOFT DRINK, BOTTLED WATER, or ICE plant, the BOTTLED WATER, SOFT DRINK, or ICE manufacturer must submit properly prepared plans and specifications for such construction, remodeling, or conversion to the DEPARTMENT for review and approval before construction, remodeling, or conversion. The plans and specifications shall indicate the proposed layout, arrangement, mechanical plans, and construction materials of work areas, and the make and model number of proposed fixed EQUIPMENT and facilities.

SECTION XI. RECIPROCITY

A. BOTTLED WATER, SOFT DRINKS, and ICE from out of state or outside the United States may be sold in South Carolina only if the DEPARTMENT determines they are manufactured and distributed under provisions substantially equivalent to the requirements of this regulation and adequately enforced.

B. Upon receiving from any PERSON, entity, or any regulatory agency outside this state a report of a possible violation of this regulation by a PERMIT HOLDER, the DEPARTMENT may conduct such inspection or investigation as it deems appropriate. Upon receiving information that SOFT DRINKS, BOTTLED WATER, or ICE manufactured outside this state and introduced into this state may have been manufactured in violation of applicable state or federal LAW, or not in conformance with prevailing and applicable standards and good public health practices, the DEPARTMENT may notify appropriate regulatory authorities located outside this state and request that such authorities take appropriate action.

SECTION XII. OUT-OF-STATE BOTTLED WATER IMPORTS

Due to additional FDA laboratory testing requirements for BOTTLED WATER products, out-of-state water bottlers shall submit the following to the DEPARTMENT: (a) a certification signed by the applicable regulatory agency with jurisdiction over the BOTTLING in the state of origin stating that the plant(s) is permitted or licensed as required, the source water supply meets all EPA public DRINKING WATER requirements, and is operated and maintained in a sanitary manner based on previous plant inspection(s); (b) the name, address, and phone number(s) of all plant(s) manufacturing bottled products for sale in South Carolina; (c) a copy of the latest finished BOTTLED WATER product water analyses (total coliform, inorganic, organic, radiological); and (d) the location(s) where the product(s) may be sampled in South Carolina.

SECTION XIII. RECALL

A. For BOTTLED WATER, SOFT DRINK, and ICE manufacturers and distributors that have not been granted a Qualified Facility Exemption by the FDA, the Recall Plan requirements of 21 CFR 117.139 supersede the requirements of this section.

B. Each SOFT DRINK, BOTTLED WATER, and ICE manufacturer and distributor shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the PERMIT HOLDER or the DEPARTMENT has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the DEPARTMENT determines, based upon representative samples, RISK analysis, information provided by the SOFT DRINK, BOTTLED WATER, or ICE manufacturer or distributor, and/or other information available to the DEPARTMENT, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the DEPARTMENT may order the SOFT DRINK, BOTTLED WATER, or ICE manufacturer and/or distributor to initiate a level of product recall

or, if appropriate, issue a form of notification to customers. Each SOFT DRINK, BOTTLED WATER, and ICE manufacturer and distributor shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION XIV. EQUIPMENT AND FACILITES IN OPERATION PRIOR TO JULY 1, 2020

A. EQUIPMENT and physical facilities of BOTTLED WATER, SOFT DRINK, and ICE plants and distribution stations in operation prior to July 1, 2020 are deemed in compliance even if they do not meet all construction, EQUIPMENT, and facilities requirements of this regulation if the facilities and EQUIPMENT:

1. are in compliance with the regulatory standards in place for such EQUIPMENT and facilities on January 1, 2020; and

2. are capable of being maintained in a sanitary condition; and

3. are not a public health hazard or nuisance; and

4. are replaced in the normal course of operation with EQUIPMENT and facilities that meet the requirements of this regulation.

B. This section shall not apply to EQUIPMENT installed or construction commenced on or after July 1, 2020.

SECTION XV. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED

When reasonable cause exists to suspect the possibility of transmission of infection from any PERSON concerned with the handling of BOTTLED WATER, SOFT DRINKS, or ICE products, or their ingredients, the DEPARTMENT is authorized to require any or all of the following measures:

A. The immediate EXCLUSION or RESTRICTION of that PERSON from handling BOTTLED WATER, SOFT DRINKS, and ICE products, or their ingredients;

B. The immediate EXCLUSION or RESTRICTION of the BOTTLED WATER, SOFT DRINKS, and ICE products concerned from distribution and use; and/or

C. ADEQUATE medical and bacteriological examination of the PERSON, of their associates, and of their bodily discharges.

SECTION XVI. ENFORCEMENT PROVISIONS

This regulation is issued under the authority of S.C. Code Ann. Sections 44-1-140 and 44-1-150 and shall be enforced by the DEPARTMENT. Any PERSON found to be in violation of this regulation, in non-compliance with an issued PERMIT, or in violation of an order issued by the DEPARTMENT shall be subject to civil monetary penalties, PERMIT suspension, and/or PERMIT revocation. Each day of continued violation shall be a separate offense.

SECTION XVII. SEVERABILITY CLAUSE

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.

~~61-54. Wholesale Commercial Ice Manufacturing.~~

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~~SECTION I. PURPOSE~~

~~This regulation sets forth minimum health standards, procedures and practices to ensure that wholesale ice is manufactured in South Carolina in a safe and wholesome manner.~~

~~SECTION II. SCOPE~~

~~This regulation shall apply to all persons in South Carolina who manufacture or package ice that will be sold on a wholesale basis for human consumption in South Carolina.~~

~~SECTION III. DEFINITIONS~~

~~ADEQUATE – shall mean substantial compliance with acceptable health standards, procedures and practices.~~

~~ADULTERATED or ADULTERATION – the presence or addition of any harmful or unwholesome substance, article, object, or other ingredients which may dilute or lower the quality of the food product involved or any substance which is prohibited by law or regulation in food product.~~

~~APPROVED – acceptable to the Department based on a determination as to conformance with applicable standards and good public health practice.~~

~~CORING – shall mean the process of pumping or removing a small amount of water that accumulates in the center of a block of ice in the freezing process. This water is mineral-laden and is removed to produce a pure, mineral-free block of ice.~~

~~DEPARTMENT – the South Carolina Department of Health and Environmental Control acting through its authorized representatives.~~

~~EASILY CLEANABLE - surfaces that are readily accessible and made of such materials and finishes and fabricated in such a way that residue may be effectively removed by normal cleaning methods.~~

~~EMPLOYEE – shall mean any person in an ice plant, or ice production area in any commercial establishment, who transports ice or ice containers, who engages in ice manufacture, processing, packaging, storage, or distribution, or who comes into contact with any ice equipment.~~

~~EQUIPMENT – all grinders, crushers, chippers, ice makers, shavers, scorers, saws, cubers, can fillers, drop tubes, needles, core sucking devices, conveyors, rake bins, augers, baggers, and similar items used in ice plants.~~

~~FOOD-CONTACT SURFACE – the surface of any object coming into direct contact with ingredients and finished products during storage and manufacture. This shall include any surface upon which the product routinely may drip, drain, or be drawn into, as part of normal processing.~~

~~ICE – shall mean the product, in any form, obtained as a result of freezing water by mechanical or artificial means.~~

~~ICE PLANT – any commercial establishment, together with the necessary appurtenances, in which ice is manufactured or processed, packaged, distributed, or offered for sale for human consumption on a wholesale basis.~~

~~ICE VENDING MACHINES – any self-service machines that act as stand-alone units, and may operate without full time service personnel. These units are activated by the insertion of money; the ice is bagged automatically or dispensed in bulk outside to the customer.~~

~~PACKAGED ICE – ice products packaged by approved manufacturers and sold through retail outlets.~~

~~PERSON – any individual, plant operator, partnership, company, corporation, trustee, association, or a public or private entity.~~

~~PEST – any animals or insects including, but not limited to, birds, rodents, flies and larvae.~~

~~PROCESSING – the grinding, crushing, flaking, cubing, or any other operation which changes the physical characteristics of ice or packaged ice for human consumption.~~

~~PRODUCT AREA – the production area and all other areas where the product, ingredients, or packaging materials are handled or stored, and shall include any area related to the manufacturing, packing, handling, and storage of ice intended for sale for human consumption.~~

~~RETAIL ICE MERCHANTS – merchants (i.e. convenience stores, grocery stores) who produce ice products and sell directly to their customers; these are regulated under DHEC Regulation 61-25, Retail Food Establishments.~~

~~SANITIZE – means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.~~

~~SHALL – the item or condition discussed is mandatory.~~

~~SHOULD or MAY – the item or condition discussed is preferred but not mandatory.~~

~~SINGLE-SERVICE ITEMS – those items, such as packaging materials, which are intended by the manufacturer and generally recognized by the public as being for one usage only, then to be discarded.~~

~~UNPACKAGED ICE – ice products from approved manufacturers that are not packaged or put into packets (usually produced in block form).~~

~~UTENSILS – any multi-use cans, buckets, tubs, pails, covers, containers, tongs, picks, shovels, scoops, and similar items used in the manufacture, handling, and transport of ice.~~

~~UNDESIRABLE MICROORGANISMS – those microorganisms which are considered to be of public health significance, which subject food to decomposition, which indicate that food is contaminated with filth, or which otherwise may cause food to be adulterated.~~

~~WHOLESALE ICE – ice products manufactured in large quantities to be sold on the wholesale market.~~

~~SECTION IV. PERSONNEL~~

~~A. DISEASE CONTROL~~

~~Any person who by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which may contribute to the reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations expected to result in such contamination, until the condition is corrected. All personnel shall be instructed to report such health conditions to their supervisors.~~

~~B. CLEANLINESS~~

~~All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. Methods for maintaining cleanliness to prevent food contamination include, but are not limited to:~~

~~1. Wearing outer garments suitable for the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.~~

~~2. Maintaining adequate personal cleanliness.~~

~~3. Washing hands thoroughly (and sanitizing, if necessary, to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. Signs shall be posted reminding employees to wash their hands before returning to work.~~

~~4. Removing all insecure jewelry or other objects which might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it should be covered by material that can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.~~

~~5. Maintaining gloves used in food handling in an intact, clean, and sanitary condition. These gloves should be of an impermeable material.~~

~~6. Where appropriate, wearing in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.~~

~~7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.~~

~~8. Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.~~

~~9. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.~~

~~C. EDUCATION AND TRAINING~~

~~Personnel responsible for identifying sanitation failures or food contamination should have a background in education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food protection principles, and should be informed of the danger of poor personal hygiene and unsanitary practices.~~

~~D. SUPERVISION~~

~~Responsibility for ensuring compliance by all personnel with all requirements of this section shall be clearly assigned to competent supervisory personnel.~~

~~SECTION V. GROUNDS, BUILDINGS AND FACILITIES~~

~~A. GROUNDS~~

~~The grounds around an ice plant under the control of the operator shall be kept in such condition to protect against the contamination of its products. The methods for adequate maintenance of grounds include, but are not limited to:~~

~~1. Properly storing equipment, removing litter and waste, and cutting weeds or grass in the immediate vicinity of plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.~~

~~2. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.~~

~~3. Adequately draining areas that may contribute to the contamination of food by seepage, foot-borne filth, or providing a breeding place for pests.~~

~~4. Operating waste treatment and disposal systems in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.~~

~~B. BUILDING CONSTRUCTION AND DESIGN~~

~~Ice plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes and to prevent drip and condensation from fixtures, ducts and pipes from contaminating foods, food-contact surfaces or food containers. Sufficient space shall be provided for the placement of equipment and storage of materials as deemed necessary for the proper maintenance of sanitary operations and production of safe food. Ice plants shall meet, but not be limited to, the following:~~

~~1. Required Rooms~~

~~Ice for human consumption shall be processed and packaged only in rooms used solely for those operations. Ice for human consumption shall not be processed or packaged on open platforms or on trucks or delivery vehicles, or in any manner which would permit contamination from overhead drip, condensation, dirt or other contaminants.~~

~~2. Floors~~

~~(a) The floors of the ice manufacturing rooms shall be constructed of concrete or equally impervious, easily cleanable material, and shall be kept clean, in good repair, and properly sloped to trapped drains to prevent pools of standing water after flushing.~~

~~(b) The floors of ice storage, packaging and accessory rooms shall be easily cleanable, and be kept clean and in good repair at all times.~~

~~3. Walls and Ceilings~~

~~The walls and ceilings in ice manufacturing, packaging, storage and accessory rooms shall be smooth, washable and kept clean and in good repair at all times.~~

~~4. Lighting~~

~~(a) Adequate lighting shall be provided in all areas of the plant. A minimum of 20 foot-candles of light should be provided in all working areas, and a minimum of 10 foot-candles in all storage areas.~~

~~(b) Adequate protection from glass breakage and falling debris shall be provided for all light bulbs and fixtures located over exposed food or unsealed packages in any step of preparation.~~

~~5. Ventilation~~

~~(a) Adequate ventilation or control equipment shall be provided to minimize odors, vapors and moisture from accumulating in areas where ice for human consumption is manufactured.~~

~~(b) Pressurized ventilating systems shall have a filtered air intake.~~

~~(c) Fans and other air-moving equipment shall be located and operated in a manner minimizing the potential for contaminating food and unsealed packages.~~

~~6. Doors and Windows~~

~~(a) All openings into ice manufacturing rooms shall be adequately protected against the entrance of dust and insects by tight-fitting, self-closing doors, closed windows, screening, air curtains, vinyl or rubber strip curtains, or by other means approved by the Department.~~

~~(b) Screens for windows, doors, skylights, transoms, intake and exhaust air ducts, and other openings into ice manufacturing rooms shall be tight-fitting and free of breaks. Screening materials shall not be less than sixteen mesh to the inch.~~

~~C. WATER SUPPLY~~

~~Each ice plant shall be equipped with adequate facilities and accommodations including, but not limited to, the following:~~

~~1. The water supply shall be from a public water system approved by the Department.~~

~~2. The design, operation and maintenance of water purification systems used to further treat potable water shall be approved by the Department. They shall not be operated beyond their rated capacity and shall be maintained in a clean, sanitary condition at all times. If water is treated at the ice plant, the use of chemicals and additives shall be in accordance with regulations promulgated under the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act.~~

~~3. Potable running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the ice manufacturing, for the cleaning of equipment, utensils, and containers, and for employee sanitary facilities.~~

~~4. All water storage and cooling tanks shall be of noncorrosive material, properly covered, air vents properly filtered, clean, free from dust both inside and outside, and the inlet and outlet so arranged as to prevent contamination during filling and emptying.~~

~~D. DISPOSAL OF WASTES~~

~~1. All liquid wastes shall be disposed of by connection to a public sewer or as approved by the Department.~~

~~2. Rubbish, refuse, and garbage shall be so handled, stored and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces and water supplies~~

~~E. PLUMBING~~

~~Plumbing shall meet all applicable state and local plumbing laws, ordinances and regulations, and shall be sized, installed and maintained to:~~

~~1. Carry sufficient quantities of water to required locations throughout the ice plant.~~

~~2. Properly convey sewage and liquid disposable waste from the ice plant.~~

~~3. Not constitute a source of contamination to foods, food products or ingredients, water supplies, equipment, or utensils or create an unsanitary condition.~~

~~4. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.~~

~~5. Prevent backflow or back-siphonage from, or cross-connection between, piping systems discharging wastewater or sewage and piping systems carrying water for ice manufacturing.~~

~~6. Non-potable water piping shall not be connected to equipment or have outlets in the brine circulation tanks.~~

~~F. TOILET FACILITIES~~

~~1. Toilet facilities shall be approved by the Department, shall be adequate, conveniently located, accessible to employees at all times, and shall conform to applicable building and plumbing codes.~~

~~2. Toilet room floors shall be easily cleanable. Toilet room floors should be properly sloped to trapped drains.~~

~~3. Toilet room walls and ceilings shall be of sound construction. Toilet room walls shall be smooth and washable to at least a wainscot height.~~

~~4. Toilet rooms shall not open directly into ice production or storage rooms.~~

~~5. Toilet room doors shall be self-closing.~~

~~6. Toilet rooms shall be adequately ventilated. Toilet room windows opened for ventilation shall be properly screened.~~

~~7. Toilet rooms shall be kept clean, in good repair and free of insects at all times.~~

~~8. Approved hand-washing signs shall be posted in each toilet room used by production employees.~~

~~9. Toilet tissue, soap, individual towels and trash receptacles shall be provided.~~

~~G. DRESSING ROOMS AND LOCKER AREAS~~

~~1. If employees routinely change clothes within the ice plant, rooms or areas shall be designated and used for that purpose and shall be kept clean and in good repair.~~

~~2. Adequate lockers or other suitable facilities shall be provided and used for the orderly storage of employee clothing and other belongings and shall be kept clean. Personnel lockers shall not be located in ice manufacturing, packaging, or storage rooms.~~

~~H. HAND-WASHING FACILITIES~~

~~1. An adequate number of lavatories, convenient to toilet rooms and production areas, shall be provided.~~

~~2. Each lavatory shall be provided with hot and cold running water, soap and approved sanitary towels, or other approved hand-drying devices. If disposable towels are used, easily cleanable waste receptacles shall be conveniently located near the hand washing facilities.~~

~~I. SANITARY OPERATIONS~~

~~1. General Maintenance~~

~~Buildings, fixtures, and other physical facilities of the ice plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the ice plant. These materials shall be identified, used only in such manner and under conditions as will be safe for their intended uses, and stored in an approved area and manner so as to minimize the danger of contamination of food and food-contact surfaces.~~

~~2. Animal and Vermin Control~~

~~No animals or birds shall be allowed in any area of the ice plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues. Insecticides and rodenticides shall be properly labeled and stored in an approved area and manner so as to minimize the danger of contamination of food and food-contact surfaces.~~

~~SECTION VI. EQUIPMENT AND UTENSILS~~

~~A. All ice plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained and kept clean and in good repair. The design, construction and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal and glass fragments, contaminated water, or any other contaminants. Only food-grade equipment lubricants shall be used and equipment lubrication shall not contaminate the ice.~~

~~B. All equipment shall be so installed and maintained to facilitate the cleaning of the equipment and all adjacent spaces.~~

~~C. All food-contact surfaces shall be corrosion-resistant when in contact with food and shall be made of nontoxic materials and designed to withstand the environment of their intended use and any corrosive action by the food, cleaning compounds and sanitizing agents. Seams on food-contact surfaces shall be smoothly bonded. Conveyor surfaces shall be of impervious material and shall protect ice from contaminants that may result from shredding, flaking, peeling, or fragmentation of the conveyor surface.~~

~~D. All equipment shall be designed to prevent food-contact surfaces from being contaminated by clothing or personal contact.~~

~~E. All equipment shall be constructed so that drip or condensation from fixtures, ducts, pipes, etc., does not contaminate food, food-contact surfaces or food-packaging materials.~~

~~F. All equipment that is in the manufacturing or food-handling areas and that does not come in contact with food shall be so constructed that it can be kept in a clean condition.~~

~~G. Approved washable covers shall be provided over exposed containers prior to filling and between filling and sealing in all areas where contamination is reasonable possible.~~

~~H. Air for water agitation shall be filtered and free of contaminants. The compressor used to supply air for water agitation shall be designed to deliver oil-free air. Air lines and core sucking (vacuum) devices shall be used as needed to produce ice free of rust or other foreign materials.~~

~~I. Ice cans shall be leak proof and the inner surfaces of such containers shall be free of corrosion. Freezing tank covers of acceptable materials shall be designed and constructed to protect ice containers from splash, drip, and other contamination. They shall be easily cleanable and kept clean and in good repair. Such covers shall be equipped with rings or similar devices when hooks are used for pulling. Can or tank covers, and the ledges or sides of the tank upon which the cover rests, shall be cleaned as often as necessary to keep them in a sanitary condition.~~

~~SECTION VII. PRODUCTION AND PROCESS CONTROLS~~

~~A. PROCESS CONTROLS~~

~~1. All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging and storing of food shall be conducted in accordance with adequate sanitation principles.~~

~~2. Appropriate quality control operators should be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the ice plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source.~~

~~3. Chemical, microbiological, or extraneous material testing procedures shall be used, where necessary, to identify sanitation failures or possible food contamination. All food that has become adulterated shall be rejected, or if permissible, treated or processed to eliminate the contamination.~~

~~4. Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into ice manufacturing and shall be stored under conditions that will protect against contamination and minimize deterioration.~~

~~5. Raw materials and other ingredients shall be properly labeled and stored in containers designed and constructed so as to protect against contamination.~~

~~6. Ice products manufactured for human consumption shall not be stored, transported, processed or bagged through equipment or lines used for any non-food product.~~

~~7. Adequate provisions shall be made so that hands shall not come in direct contact with the ice at any time during manufacturing, processing, packaging, and storage.~~

~~8. Packaging shall be done with non-toxic materials and in a sanitary manner. All packaged ice products must be tightly sealed. Bags used for the packaging of ice shall be stored in a dry rodent and dust proof environment. The storage of packaging supplies shall be on pallets or raised above floor level and all partially used supplies shall be kept in closed containers. The bags shall be of sound strength and quality to prevent fracture or tearing during handling and be constructed of FDA approved materials. Bags shall be restricted for reuse, or repackaging.~~

~~9. All frozen unpackaged ice blocks intended for sale for human consumption or for the refrigeration of food products shall be washed thoroughly with potable water, packed and handled in a manner to prevent contamination. Water used for rinsing or washing shall not be reused and shall be disposed of as liquid waste. Only potable water shall be used in sprays and in the thaw tanks for the removal of ice from cans. Ice shall not come in direct contact with water in dipping wells.~~

~~B. CLEANING AND SANITIZING OF EQUIPMENT AND UTENSILS~~

~~All utensils and food-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Non food-contact surfaces of equipment used in the operation of ice plants shall be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles and other debris. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and food-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruptions during which such utensils and food-contact surfaces may have become contaminated. Where such equipment and utensils are used in a continuous production operation, the food-contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. All cleaning and sanitizing agents shall be free of undesirable microorganisms, shall be safe and adequate under the conditions of use, shall have labels which properly identify the contents, and shall be properly stored. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment. All cleaned and sanitized equipment and utensils shall be transported and stored to assure complete drainage and stored in a manner that protects the food-contact surfaces from contamination.~~

~~SECTION VIII. WAREHOUSING AND DISTRIBUTION~~

~~A. All product storage and holding areas are to be refrigerated and shall be cleaned as often as necessary to keep them free of contamination.~~

~~B. While being transported or delivered, ice shall be protected from contamination from dust, dirt, or any other sources. The ice compartment of vehicles used to transport or deliver ice shall be of cleanable construction and shall be kept clean and in good repair. The ice compartment used for transport or delivery shall be insulated or refrigerated to maintain the ice in a frozen state. Vehicles used to transport unpackaged ice shall be constructed to be fully enclosed. All interior surfaces shall be constructed of food grade quality materials and shall be thoroughly cleaned prior to each loading.~~

~~SECTION IX. LABELING~~

~~All packaged ice labeling shall conform to applicable federal and state labeling laws.~~

~~SECTION X. EXAMINATION AND CONDEMNATION OF UNWHOLESOME OR CONTAMINATED RAW MATERIALS OR FINISHED PRODUCT~~

~~A. Samples of ice and other substances shall be taken and examined by the Department as often as may be necessary for the detection of unwholesomeness or adulteration.~~

~~B. The Department may condemn and forbid the sale of, or cause to be removed and destroyed, any ice or products which are unwholesome or adulterated.~~

~~SECTION XI. ICE VENDING MACHINES~~

~~A. Owner/operators of ice vending machines within the state must file an application provided by the Department. This application shall include name and address of ice vending machine's owner/operator, location, products to be manufactured, applicant's signature and such other information deemed necessary by the Department to determine compliance with this regulation. However, no permit will be issued. This information will be held on file for the purpose of compliant investigations or product sampling for detection of unwholesomeness or adulteration, or any other circumstance which may constitute an imminent hazard to public health.~~

~~B. All ice vending machines must be properly connected to Department approved water supply and sewage disposal facilities.~~

~~SECTION XII. ENFORCEMENT PROCEDURES~~

~~A. PERMITS~~

~~1. It shall be unlawful for any person to manufacture wholesale ice products in South Carolina without a valid permit issued by the Department for the specific ice plant. Permits are not transferable.~~

~~2. Any person desiring to manufacture wholesale ice products in South Carolina shall make written application for a permit on the appropriate application form provided by the Department. This form shall include name and address of the ice plant's owner; the location and type of the facility; the type of products to be manufactured; the applicant's signature; and such other information deemed necessary by the Department to determine compliance with this regulation.~~

~~3. A permit is valid as long as the ice plant continues in operation under the same ownership or until the permit is revoked or suspended.~~

~~4. Any retail facility that produces and bags ice for sale to the public shall have a permit issued under Regulation 61-25, Retail Food Establishments.~~

~~B. SUBMISSION OF PLANS~~

~~When an ice plant is constructed or extensively remodeled and when an existing structure is converted for use as an ice plant, properly prepared plans and specifications for such construction, remodeling, or conversion should be submitted to the Department for review and approval before construction, remodeling, or conversion. The plans and specifications should indicate the proposed layout, arrangement, mechanical plans, and construction materials of work areas, and the make and model number of proposed fixed equipment and facilities. The Department shall approve the plans and specifications if they meet the requirements of this regulation. In the absence of plan approval, issuance of the ice plant permit shall be determined by compliance with all applicable requirements of this regulation.~~

~~C. INSPECTIONS~~

~~Inspections of ice plants shall be performed as frequently as deemed necessary to insure compliance with this regulation.~~

~~D. ACCESS~~

~~Representatives of the Department, after proper identification, shall be permitted to enter any ice plant at any reasonable time for the purpose of making inspections to determine compliance with this regulation. The representatives shall be permitted to examine the records of the establishment to ascertain information relative to the purchasing, receiving, and use of such food products or other supplies used in the manufacturing of wholesale ice products. It shall be unlawful for any representatives of the Department who, in an official capacity, obtain any information under the provisions of this regulation which is entitled to protection as a trade secret (including information as to quantity, quality, source or disposition of wholesale ice products, or results of inspections or tests thereof) to use such information to their own advantage or to reveal it to any unauthorized person.~~

~~E. REPORT OF INSPECTIONS~~

~~When an inspection of an ice plant is conducted, a copy of the completed inspection report form shall be furnished to the permit holder, manager or other duly authorized representative.~~

~~F. RECIPROCITY~~

~~Upon receiving from any person, entity, or any regulatory agency outside this state, a report of a possible violation of this regulation by a permit holder, the Department may conduct such inspection or investigation as it deems appropriate. Upon receiving information that wholesale ice products manufactured in the state or imported from other states and introduced into this state may have been manufactured in violation of applicable state or federal law or not in conformance with prevailing and applicable standards and good public health practices, the Department may notify appropriate regulatory authorities located outside this state and request that such authorities take appropriate action.~~

~~G. RECALL~~

~~Each ice plant operator shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any of these procedures as necessary with respect to any product for which the operator or the Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the Department determines, based upon representative samples, risk analysis, information provided by the ice supplier, and other~~

~~information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the ice supplier to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The ice supplier shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.~~

~~H. SUSPENSION OF PERMIT~~

~~1. Permits may be suspended temporarily by the Department for repeated violation of the same requirement on two consecutive inspections, for total number of violations, or for interference with the Department in the performance of its duty. Prior to permit suspension, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be suspended and that the permit shall be suspended at the end of the 15 days following service of such notice. While the permit is suspended, ice operations shall immediately cease, and the permit shall remain suspended until the reasons for the suspension have been corrected.~~

~~2. The Department may, without warning or notice, suspend the permit to operate an ice plant when it is determined that the operation of the ice plant constitutes an imminent hazard to public health. Following immediate permit suspension, all ice manufacturing operations shall immediately cease. The Department shall promptly notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit was suspended.~~

~~I. REVOCATION OF PERMIT~~

~~1. The permit may be revoked for failure to correct deficiencies within prescribed time limits or for repeated violations of any of the requirements of this regulation on two consecutive inspections, or for the interference with the Department in the performance of duty.~~

~~2. Prior to revocation, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be revoked and that the permit shall be revoked at the end of the 15 days following service of such notice.~~

~~3. Any person whose permit is revoked shall not be eligible to apply for repermitting within one year from the date of revocation. Any person whose permit has previously been revoked and who obtains a subsequent permit and violates the provisions of this regulation, resulting in revocation of the ice plant's permit for the second time, shall not be granted another permit.~~

~~J. SERVICE OF NOTICES~~

~~A notice provided for in this regulation is properly served when it is delivered to the permit holder, manager or other duly authorized representative, or when it is sent by registered or certified mail, return receipt requested and delivery restricted to the addressee, to the last known address of the ice plant's permit holder.~~

~~K. CONTESTED DECISIONS~~

~~A Department decision involving the issuance, denial, suspension, or revocation of a permit may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.~~

~~L. ENFORCEMENT PROVISIONS~~

~~This regulation is issued under the authority of South Carolina Code Ann. Section 44-1-140 (1976, as amended) and shall be enforced by the Department. Violation of this regulation shall be punishable in accordance with South Carolina Code Ann. Section 44-1-150 (1976, as amended).~~[Repealed].

ATTACHMENT B
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-140 and 44-1-150

Notice of Drafting:

The Department of Health and Environmental Control ("Department" or "DHEC") proposes amending R.61-32, Soft Drink and Water Bottling Plants. The Department further proposes amending the requirements of R.61-54, Wholesale Commercial Ice Manufacturing, and merging it into R.61-32. This will entail repealing R.61-54 and adding its amended requirements to R.61-32.

Interested persons may submit written comments to Sandra D. Craig, Director, Division of Food and Lead Risk Assessments, Bureau of Environmental Health Services, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201, or by email at craigsd@dhec.sc.gov. To be considered, written comments must be received no later than 5:00 p.m. on May 28, 2019, the close of the drafting comment period.

Synopsis:

The Department proposes amending R.61-32 and the requirements of R.61-54. Currently, R.61-32 and R.61-54 are both based on federal regulations found in the Code of Federal Regulations ("CFR"), 21 CFR Part 110, which was replaced with 21 CFR Part 117 on September 1, 2018. The Department proposes amending R.61-32 and R.61-54 to incorporate the requirements of 21 CFR Part 117. In the interest of efficiency, the Department proposes repealing R.61-54and merging its amended requirements into R.61-32. The Department further proposes renaming the regulation R.61-32, Wholesale Commercial Bottled Water, Soft Drink, and Ice Manufacturing. The Department also proposes amendments not required by federal law, including additions, updates, and clarifications to administrative requirements, enforcement requirements, and definitions.

The Department may also propose stylistic changes such as corrections for clarity and readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments and repeal, as portions of the above-referenced proposed amendments include updates or other changes to R.61-32 and R.61-54 that are not addressed by the federal regulations.

(x) ACTION/DECISION
( ) INFORMATION

Date: September 12, 2019

To: S.C. Board of Health and Environmental Control

From: Bureau of Environmental Health Services

Re: Notice of Proposed Regulation Amending R.61-36, *Frozen Desserts*, and Repealing R.61-35, *Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products.*

I. Introduction

The Bureau of Environmental Health Services (Bureau) proposes the attached Notice of Proposed Regulation amending R.61-36, *Frozen Desserts*. The Bureau further proposes revising the requirements of R.61-35, *Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products*, and merging it into R.61-36, *Frozen Desserts*. This entails repealing R.61-35, *Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products* and adding its amended requirements to R.61-36, *Frozen Desserts*. Along with merging these regulations, the Department proposes adding regulatory requirements for manufacturing cheese, butter, and other non-grade "A" milk products to R.61-36, *Frozen Desserts* and changing its title. The Bureau presents this proposal for publication in the September 27, 2019, *South Carolina State Register* (*State Register*). Legal authority resides in S.C. Code Sections 44-1-140 and 44-1-150, which allow the Department of Health and Environmental Control (Department) to promulgate regulations for the production, storing, labeling, transportation, and selling of milk and milk products, filled milk and filled milk products, imitation milk and imitation milk products, synthetic milk and synthetic milk products, milk derivatives, and any other products made in semblance of milk or milk products. Furthermore, 44-1-150 allows for the enforcement of orders related to violations of these regulations. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments and repeal. R.61-36 was last amended in 2004 and R.61-35 was last amended in 1976.

II. Facts

1. The purpose of R.61-36, *Frozen Desserts*, and R.61-35, *Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products*, is to safeguard public health and provide consumers safe, unadulterated frozen dessert and imitation dairy food products manufactured in South Carolina to be sold and distributed both in state and out of state. These regulations govern the production, processing, storing, labeling, transportation, and distribution of frozen desserts and imitation dairy foods that are not regulated as "Grade A" milk under the provisions of R.61-34, *Raw Milk for Human Consumption*, or R.61-34.1, *Pasteurized Milk and Milk Products*. The current regulations are based on Title 21, *Food and Drugs,* Part 110 *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food* of the Code of Federal Regulations (CFR) (21 CFR Part 110), which has now been replaced by 21 CFR Part 117 *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food.* The new federal regulation updates good manufacturing processes and incorporates new preventive controls for minimizing or preventing food safety hazards.

2. The Bureau proposes amending the provisions of R.61-36 and R.61-35 to incorporate standards of the new federal regulation. The structure of the federal regulation also facilitates combining provisions governing all manufactured dairy products into one streamlined regulation, instead of two separate regulations with repetitive content. As part of this new streamlined regulation, the Department also proposes

adding requirements for manufacturing cheese, butter, and other non-grade "A" milk products. The South Carolina Department of Agriculture previously regulated cheese and butter products (also under 21 CFR Part 110 *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food*); however, oversight now resides with the DHEC.

3. To achieve this more functional, streamlined regulation, the Department proposes repealing R.61-35 and combining its revised provisions into R.61-36. This also includes amending the title of R.61-36 to "Manufactured Grade Dairy Products." The proposed amendments also include other changes not required by federal law, including updates from the current Pasteurized Milk Ordinance ("PMO") and additions, updates, and clarifications to administrative requirements, enforcement requirements, and definitions, as well as other changes deemed necessary by the Department to improve the overall clarity, organization, and quality of the regulation.

4. The Department had a Notice of Drafting published in the April 26, 2019, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments by the May 28, 2019, close of the public comment period.

5. The Bureau held stakeholder meetings on July 18, 2019, in Charleston and July 25, 2019, in Anderson. The Bureau emailed information for meeting attendance to all permitted facilities, along with a proposed draft of the regulation to facilitate discussion. The Department also posted the information and draft regulation on the DHEC manufactured food web page to reach as broad an audience as possible.

6. Appropriate Department staff conducted an internal review of the proposed amendments and repeal on July 29, 2019.

7. The proposed amendments to these regulations serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements. In addition to clarification and updating of state-specific regulatory provisions, these proposed amendments incorporate current federal standards, which have replaced preexisting federal standards upon which the Department's existing, unrevised regulations are based. This serves to reduce administrative burdens on the regulated community by facilitating streamlined inspections and compliance under both state and federal requirements.

III. Request for Approval

The Bureau respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 27, 2019, *State Register*.

Renee G. Shealy, Chief
Bureau of Environmental Health Services

Myra C. Reece, Director
Environmental Affairs

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the April 26, 2019, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-36, *Frozen Desserts*, and R.61-35, *Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products*.

September 12, 2019

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-140(3) and 44-1-150

61-35. Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products.
61-36. Frozen Desserts.

Preamble:

The purpose of R.61-36, Frozen Desserts, and R.61-35, Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products, is to safeguard public health and provide consumers safe, unadulterated frozen dessert and imitation dairy food products manufactured in South Carolina to be sold and distributed both in state and out of state. These regulations govern the production, processing, storing, labeling, transportation, and distribution of frozen desserts and imitation dairy foods that are not regulated as "Grade A" milk under the provisions of R.61-34, Raw Milk for Human Consumption, or R. 61-34.1, Pasteurized Milk and Milk Products. The regulations are based on Title 21, Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food of the Code of Federal Regulations (CFR) (21 CFR Part 110).

The Department of Health and Environmental Control (Department) last amended R.61-36 in 2004. Earlier this year, 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food was replaced by 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food. There have been numerous changes in the manufactured food industry, including changes to food handling practices, food equipment technology, and food preparation processes, making R.61-36, Frozen Desserts, and 61-35, Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products, outdated. The new federal regulation updates good manufacturing processes and incorporates new preventive controls for minimizing or preventing food safety hazards.

The Department proposes amending the provisions of R.61-36 and R.61-35 to incorporate standards of the new federal regulation. The structure of the federal regulation also facilitates combining provisions governing all manufactured dairy products into one streamlined regulation, instead of two separate regulations with repetitive content. As part of this new streamlined regulation, the Department also proposes adding requirements for manufacturing cheese, butter, and other non-grade "A" milk products. The South Carolina Department of Agriculture previously regulated cheese and butter products (also under 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food); however, oversight now resides with the DHEC.

To achieve this more functional, streamlined regulation, the Department proposes repealing R.61-35 and combining its revised provisions into R.61-36. This includes amending the title of R.61-36 to "Manufactured Grade Dairy Products."

The proposed amendments also entail changes not required by federal law, including updates from the current Pasteurized Milk Ordinance (PMO) and additions, updates, and clarifications to administrative requirements, enforcement requirements, and definitions, as well as other changes deemed necessary by the Department to improve the overall clarity, organization, and quality of the regulation. These changes include stylistic changes such as corrections for clarity and readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments and repeal.

The Department had a Notice of Drafting published in the April 26, 2019, South Carolina State Register.

Section-by-Section Discussion of Proposed Amendments and Repeal:

R.61-35 is stricken in its entirety and repealed.

R.61-36 is stricken in its entirety and replaced with the combined, revised text of R.61-35 and R.61-36. Butter and cheese production requirements are also added. The discussion section below details specific changes to the existing, unrevised R.61-35 and R. 61-36.

The Table of Contents reflects the new proposed language. Some sections have been moved and/or renamed to streamline the regulation and to reflect changes in administrative processes.

Replaced in all sections and titles, "frozen desserts" with "manufactured grade dairy products" where applicable.

Formatting was changed to reflect the lettering of sections as opposed to numbering to harmonize with other manufactured food regulations.

In Section I. DEFINITIONS, the following changes apply:

61-36.I.B. Added: “Alcohol Infused Frozen Desserts” to distinguish these products from non-alcoholic desserts.

61-36.I.C. Added: “Approved” to clarify standards for approval.

61-36.I.F. Added: “Business Day” to provide clarity on compliance time requirements.

61-36.I.G. Added: “Butter” and sub-categories of butter as a new food product included in this regulation.

61-36.I.H. Added: “CFR” to define the code of federal regulations.

61-36.I.I. Added: “Cheese” as a new food product included in this regulation.

61-36.I.L. Added: “Employee” to clarify who is defined by this role.

61-36.I.M. Added: “Exclusion” to clarify that it is related to preventing an employee from entering or working in a manufactured grade dairy products plant or distribution station.

61-36.I.N. Added: “FDA” to clarify that this refers to the United States Food and Drug Administration.

61-36.I.O. Added: “FD&C” to clarify that this refers to the United States Food, Drug, and Cosmetic Act.

61-36.I.T. Added: “Imminent Health Hazard” to clarify public health hazards requiring immediate action.

61-36.I.U. Added: “Law” to clarify that it applies to local, state, and federal codes.

61-36.I.V.-AA. Amended: Previous definitions for frozen desserts to reflect new definitions for manufactured grade dairy products, distribution stations, distributors, manufacturers, plants, and retailers.

61-36.I.BB. Added: “Microorganisms” as defined in 21 CFR 117.3.

61-36.I.CC. Added: “Milk” to define that it only applies to hooved mammals’ lacteal secretions.

61-36.I.EE. Added: “Nuisance” to clarify that it pertains to structures and premises that represent a danger to public health.

61-36.I.HH. Amended: “Pasteurization” to update the time and temperature charts to be consistent with the current PMO and provisions of the FD&C Act.

61-36.I.II. Added: “Pathogen” to define that it is a microorganism of public health concern.

61-36.I.JJ-KK. Added: “Permit” and “Permit Holder” to clarify for compliance and documentation purposes.

61-36.I.MM. Added: “Pest” to clarify that it refers to any objectionable animals and insects.

61-36.I.NN. Added: “PMO” to clarify that it refers to the Pasteurized Milk Ordinance.

61-36.I.OO. Added: “Premises” to clarify all of the potential areas covered under this regulation.

61-36.I.PP. Added: “Raw Milk” to clarify that this is milk that has not been pasteurized.

61-36.I.QQ. Added: “Restriction” to clarify that this is related to limiting the activities of an employee as it relates to working in a manufactured grade dairy products plant or distribution station.

61-36.I.RR. Added: “Retail Food Establishment” to clarify that these are establishments that sell directly to the end consumer.

61-36.I.SS. Added: “Risk” to clarify that this is related to a public health hazard.

61-36.I.TT. Amended: “Sanitize” to reflect the current science related to destroying pathogens on surfaces.

61-36.I.VV. Added: “Unexposed Packaged Food” to clarify that it is packaged food that has not been exposed to the environment.

Added: That additional related definitions are found in 21 CFR 117.3.

In Section II. ADULTERATED OR MISBRANDED MANUFACTURED GRADE DAIRY PRODUCTS, the following changes apply:

61-36.II.B. Added: to address the scope of the regulation of alcohol infused frozen desserts by DHEC.

61-36.II.C. Amended: C. to address when a hold order may be issued.

61-36.II.D. Amended: to address suspension of permits when hold orders are violated.

61-36.II.E. Added: to address condemnation of food.

61-36.II.F. Added: to address notice and issuance of hold orders.

61-36.II.G. Added: to address examination of products for adulteration or misbranding and the storage of products under a hold order.

61-36.II.H. Added: to address products adulterated by drugs or poisonous substances.

In Section III.COMPLIANCE PROCEDURES, the following changes apply:

61-36.III.A. Amended: to clarify permit requirements.

61-36.III.B.1. Amended: to add violation of an order issued by the Department to this section.

61-36.III.B.2. Amended: to clarify requirements governing summary permit suspension.

61-36.III.B.4. Amended: to clarify timeframe for re-inspection or sampling.

61-36.III.C.1. Amended: to add violation of an order issued by the Department to this section.

61-36.III.C.2. Amended: to include clarification of inspection and enforcement history as it relates to non-compliance.

61-36.III.C.3. Amended: to clarify process for re-applying for a new permit once a permit is revoked.

Former 61-36.III.C.2 and 6. Deleted detail on notice and hearing procedures implemented by the Department.

In Section IV. LABELING, the following changes apply:

61-36.IV. Amended: deleted outdated language and added that products must be labeled according to 21 CFR Part 101.

In Section V. INSPECTION OF MANUFACTURED GRADE DAIRY PRODUCTS PLANTS AND MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS, the following changes apply:

61-36.V.B. Amended: to adjust frequency of inspections to be determined by the risk level of the product.

61-36.V.C. Deleted: renumbered remaining sections.

61-36.V.D. Amended: to clarify mix must meet PMO standards and added "health" to imminent hazard.

61-36.V.E. Amended: to allow for electronic or paper inspection reports and clarify delivery method.

61-36.V.G .Amended: to remove unnecessary verbiage.

In Section VI. THE EXAMINATION OF MANUFACTURED GRADE DAIRY PRODUCTS

61-36.VI.A.1. Amended: to adjust frequency of sampling to be determined by the risk level of the product.

61-36.VI.A.2. Amended: and combined with deleted A.3. to clarify locations from which samples may be taken.

61-36.VI.B.1. Amended: to remove outdated procedures and to add and new a. and b. with current sampling frequencies and standards.

61-36.VI.B.2. Amended to clarify that the permit holder is responsible for determining the cause of improper pasteurization of product.

In Section VII. STANDARDS FOR MANUFACTURED GRADE DAIRY PRODUCTS, PLANTS AND MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS

61-36.VII.A.1.a. Amended: to require that milk and milk products used to produce manufactured grade dairy products must come from an approved source.

61-36.VII.A.1.a.1-4. Deleted: as outdated or redundant to other sections.

61-36.VII.A.2. Amended: replaced the entire section with requirements specific to the production of cheese.

61-36.VII.A.3. Added: a new section with requirements specific to the production of butter.

61-36.VII.A.4. Added: a new section to clarify processes for deactivating microorganisms.

61-36.VII.A.5. Added: to address imitation milk and milk products from current R. 61-35.

61-36.VII.B. Added: relocated section on Post Pasteurization Ingredients.

61-36.VII.C. Deleted: the entire section and replaced with new language that requires compliance with requirements of 21 CFR Part 117, Subpart B - Current Good Manufacturing Practice.

61-36.VII.C.1.a. Added: requires compliance with 7 CFR 58.311-321 and 7 CFR 58.332-344 for butter manufacturers.

61-36.VII.C.1.b. Added: requires compliance with 7 CFR 58.406-429 and 7 CFR 58.428-445 for cheese manufacturers.

61-36.VII.C.2. Deleted: the entire section and replaced with new language that requires compliance with requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart D - Modified Requirements, Subpart F- Requirements Applying to Records That Must Be Established and Maintained and be familiar with Subpart E Withdrawal of a Qualified Facility Exemption.

61-36.VII.C.3. Deleted: the entire section and replaced with new language that requires compliance with requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing

Practice, Subpart C - Hazard Analysis and Risk-Based Preventive Controls, and Subpart F- Requirements Applying to Records That Must Be Established and Maintained.

61-36.VII.C.4. Deleted: the entire section and replaced with new language that requires compliance with requirements of 21 CFR Part 117.

61-36.VII.C.5. Deleted: the entire section and replaced with new language that requires compliance with requirements of 21 CFR Part 117 Subpart G - Supply-Chain Program.

61-36.VII.C.6. Amended: to clarify and simplify the requirement for separate processing rooms.

61-36.VII.C.7. Amended: to clarify who must have an approved public water supply and the examination and records requirements.

61-36.VII.C. 8-22. Deleted: as these requirements are in 21 CFR Part 117 as referenced in sections above.

In Section VIII. MANUFACTURED GRADE DAIRY PRODUCTS FROM OUT OF STATE OR OUTSIDE THE UNITED STATES

61-36.VIII. Amended: the section to update the language related to products manufactured and imported into South Carolina for distribution.

Renumbered remaining sections.

In Section IX. PLANS FOR CONSTRUCTION AND RECONSTRUCTION

No changes to this section

In Section X. EQUIPMENT AND FACILITES IN OPERATION PRIOR TO JULY 1, 2020

61-36.X. Amended: Re-titled and replaced the content of this entire section with new content on allowing equipment and facilities approved under previous versions of this regulation to be accepted as long as they are capable of being maintained in a sanitary condition and are not creating a health hazard. Renumbered remaining sections.

In Section XI. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED

61-36.XI. Amended: updated the language in this section to clarify when and how to restrict and exclude ill food employees.

In Section XII. RECALLS

61-36.XII. Amended: to reference 21 CFR Part 117.139 if applicable and, if not applicable, state the requirements for a procedure for developing a recall plan.

In Section XIII. ENFORCEMENT AND PENALTIES

61-36.XIII. Amended: re-titled and replaced the entire section with language that reflects current laws.

In Section XIV. SEVERABILITY CLAUSE

No change

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed amendments and repeals to Sandra Craig of the Bureau of Environmental Health Services; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; craigsd@dhec.sc.gov. To be considered, the Department must receive the comment(s) by 5:00 p.m. on October 28, 2019, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed amendments and repeals during its December 12, 2019, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agency/docs/AGENDA.PDF.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/.

Preliminary Fiscal Impact Statement

There are no anticipated new costs associated with the implementation of this regulation to the state or its political subdivisions.

Statement of Need and Reasonableness

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-35, Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products, and 61-36, Frozen Desserts.

Purpose: This amendment strikes the text of the existing regulations in total, repeals the text of R.61-35, combines the revised text of both to align with current standards of the most recent edition of the CFR, and includes provisions for the regulation of additional non-grade "A" dairy products, such as cheese and butter. The existing regulations are based on 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, which has been replaced with 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food. The new federal regulation updates good manufacturing processes to be implemented by the regulated community and also incorporates new preventive controls for minimizing or preventing food safety hazards. The PMO also has been recently updated, and the necessary provisions for pasteurization of fluid milk used in the production of these products have been incorporated into this revision. The new federal regulation facilitates combining all manufactured dairy products into one streamlined regulation, instead of two separate regulations with repetitive content.

Legal Authority: 1976 Code Sections 44-1-140(3) and 44-1-150

Plan for Implementation: The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to these proposed amendments and repeals. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the amendments and repeals and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The purpose of R.61-36, Frozen Desserts, and R.61-35, Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products, is to safeguard public health and provide consumers safe, unadulterated frozen dessert and imitation dairy food products manufactured in South Carolina to be sold and distributed both in state and out of state. These regulations govern the production, processing, storing, labeling, transportation, and distribution of frozen desserts and imitation dairy foods that are not regulated as "Grade A" milk under the provisions of R.61-34, Raw Milk for Human Consumption, or R. 61-34.1, Pasteurized Milk and Milk Products. The regulations are based on Title 21, Part 110 of the Code of Federal Regulations (CFR) (21 CFR Part 110).

The Department of Health and Environmental Control (Department) last amended R.61-36 in 2004. Earlier this year, 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food was replaced by 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food. There have been numerous changes in the manufactured food industry, including changes to food handling practices, food equipment technology, and food preparation processes, making R.61-36 and 61-35 outdated. The new federal regulation updates good manufacturing processes and incorporates new preventive controls for minimizing or preventing food safety hazards.

The Department proposes amending the provisions of R.61-36, Frozen Desserts, and R.61-35, Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products to incorporate standards of the new federal regulation. The structure of the federal regulation also facilitates combining provisions governing all manufactured dairy products into one streamlined regulation, instead of two separate regulations with repetitive content. As part of this new streamlined regulation, the Department also proposes adding requirements for manufacturing cheese, butter, and other non-grade "A" milk products. The South Carolina Department of Agriculture previously regulated cheese and butter products (also under 21 CFR Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food); however, oversight now resides with the Department. Furthermore, the U.S. Food and Drug Administration (FDA) recently updated the PMO, and the necessary provisions for pasteurization of fluid milk used in the production of these products have been incorporated into this proposed revision.

The proposed amendments to these regulations serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements. In addition to clarification and updating of state-specific regulatory provisions, these proposed amendments incorporate current federal standards, which have replaced preexisting federal standards upon which the Department's existing, unrevised regulations are based. This serves to reduce administrative burdens on the regulated community by facilitating streamlined inspections and compliance under both state and federal requirements.

DETERMINATION OF COSTS AND BENEFITS:

There are no anticipated new costs associated with the implementation of this regulation. The proposed amendments will benefit public health by ensuring safe, unadulterated dairy food and dairy food products

at manufacturing plants and throughout the distribution chain. The proposed amendments to these regulations also serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements. The amendment of R.61-36 to align with the most recent edition of the CFR and incorporate the most recent changes to the PMO will allow the regulation to conform to the current national standards. Industry will benefit by having an aligned set of rules to comply with for federal inspections that may be conducted by the FDA, those conducted by the Department for the FDA, and those conducted for the state under this regulation. Such alignment also allows for facilities to undergo one inspection, conducted by the Department under this regulation, to satisfy both federal and state oversight. The amendments also combine provisions governing different manufactured dairy products into one streamlined regulation, instead of two separate regulations with repetitive content.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Implementation of this regulation will not compromise the protection of the environment or the public health. The proposed regulation will help to ensure that consumers are receiving safe, unadulterated dairy food and dairy food products. The amendment of R.61-36 to conform to the most recent edition of the CFR also provides effective means of reducing the risks of foodborne illnesses within dairy food manufacturing plants, thus protecting consumers and industry from potentially devastating public health consequences and financial loss. Incorporation of the Food Safety Modernization Act compliant 21 CFR Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls For Human Food and the new preventive controls for minimizing or preventing food safety hazards allows for better training and understanding of risk by those in charge of food safety in processing plants.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There will be no adverse effect on the environment if the regulations are not implemented.

Failure to adopt these amendments would prevent implementation of the latest sanitary standards and a comprehensive approach to food safety management needed in addressing food protection in the manufactured dairy products industry. This could have a detrimental effect on the health of South Carolina's citizens and visitors.

Statement of Rationale:

The Department proposes these amendments to meet the latest sanitation requirements for providing safe, unadulterated manufactured grade dairy products to consumers. Furthermore, the amendments allow for one inspection, conducted by the Department under this regulation, to satisfy both federal and state oversight. The amendments also combine provisions governing different manufactured grade dairy products into one streamlined regulation, instead of two separate regulations with repetitive content.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

~~61-35. Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products.~~

~~SECTION 1. Definitions.~~

~~A. Imitation milk and milk products are products which are made to resemble in form and are intended to be used as substitutes for milk and/or milk products as defined in the South Carolina Department of Health and Environmental Control's Rules and Regulations Governing Milk and Milk Products and which have been determined to be nutritionally inferior to the milk or milk products they are intended to imitate. (The standards for milk and milk products as published in the Milk Industry Foundation Labeling Manual, March 1974, will be used to determine if a product is nutritionally inferior.)~~

~~B. Products made in semblance of milk and milk products are products which are made to resemble in form and are intended to be used in substitution for milk and/or milk products and which are determined not to be nutritionally inferior to milk and/or milk products.~~

~~C. The fat content and solids not fat for imitation milk, imitation milk products, and products made in semblance of milk and milk products shall meet the minimum standards for the milk or milk product which it imitates or resembles. To each quart of imitation milk, imitation lowfat milk, imitation skim milk, and products made in semblance of these products, 400 U.S.P. units of Vitamin D and 2000 U.S.P. units of Vitamin A shall be added.~~

~~D. Any imitation milk, imitation milk products and products made in semblance of milk and milk products shall be deemed to be adulterated (1) if it bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health; (2) if it bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by State or Federal regulation, or in excess of such tolerance if one has been established; (3) if it consists, in whole or in part, of any substance unfit for human consumption; (4) if it has been produced, processed, prepared, packed, or held under insanitary conditions; (5) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.~~

~~E. Imitation milk, imitation milk products and products made in semblance of milk and milk products are misbranded (1) when their container(s) bear or accompany any false or misleading written, printed or graphic matter; (2) when such products do not conform to their definitions as contained in these regulations, and (3) when such products are not labeled in accordance with Section 2 of these regulations.~~

~~SECTION 2. Labeling.~~

~~A. The label must be readable and understandable and shall not contain any misleading or false statements. All ingredients must be identified by their common name, and nutritional information must be shown. Vegetable and animal fats used must be identified by source. Imitation products shall be labeled "Imitation" followed by the name of the milk or milk product imitated. Labels for imitation products containing no dairy ingredient shall also show the term "non-dairy product". Imitation products containing dairy products and/or dairy ingredients shall show, following the name of the imitation products, the name of the specific dairy product(s) and/or dairy ingredient(s) contained.~~

~~B. Products made in semblance of milk and milk products shall comply with labeling requirements stated in Section #2A, for imitation milk and milk products. A fanciful name may be used and/or the word "imitation".~~

~~SECTION 3. Sanitation, Bacteriological, Chemical, and Temperature Standards.~~

~~Sanitation requirements for processing, packaging, and distribution of imitation milk, imitation milk products, and products made in semblance of milk and milk products shall be the same as those for Grade A pasteurized milk and milk products. (Section 7, Item IP-22P, Rules and Regulations Governing Milk and Milk Products, South Carolina Department of Health and Environmental Control, 1968, as amended). Chemical, bacteriological, and temperature standards shall be the same as those shown for Grade A pasteurized milk and milk products. (Section 7, Chemical, Bacteriological, and Temperature Standards for Grade A Milk and Milk Products, Rules and Regulations Governing Milk and Milk Products, South Carolina Department of Health and Environmental Control, 1968, as amended).~~

~~SECTION 4. Adulterated or Misbranded Imitation Milk, Imitation Milk Products and Products Made in Semblance of Milk and Milk Products.~~

~~No person shall within the state of South Carolina or its police jurisdiction, process, provide, sell, offer, or expose for sale, or have in possession with intent to sell any imitation milk, imitation milk products or products made in semblance of milk and milk products which is adulterated or misbranded. Any adulterated or misbranded imitation milk, imitation milk product or products made in semblance of milk and milk products may be impounded by the Department of Health and Environmental Control and disposed of in accordance with applicable laws and regulations.~~

~~Imitation milk, imitation milk products and products made in semblance of milk or milk products shall be examined or sampled by the Department of Health and Environmental Control as often as necessary to determine freedom from adulteration or misbranding. The Department of Health and Environmental Control may upon written notice to the owner or person in charge place a hold order on any imitation milk, imitation milk products, or products made in semblance of milk and milk products which he determines or has probable cause to believe to be unwholesome or otherwise adulterated or misbranded. Under a hold order, products shall be permitted to be suitably stored.~~

~~SECTION 5. Permits.~~

~~It shall be unlawful for any person who does not possess a permit from the Department of Health and Environmental Control to process and package, have in storage, or otherwise offer for sale any products defined in these regulations.~~

~~In addition, requirements contained in Section 3 "Permits" in the Rules and Regulations Governing Milk and Milk Products, South Carolina Department of Health and Environmental Control, 1968, as amended, which are applicable shall be required for the processing, storage and offering for sale of products defined.~~

~~SECTION 6. Inspections of Plants.~~

~~Each plant, storage facility, and distribution station located in South Carolina whose products are defined in these regulations shall be inspected by the South Carolina Department of Health and Environmental Control prior to the issuance of a permit. Following the issuance of a permit, each plant, storage facility, and distribution station shall be inspected at least once every three months. Should the violation of any sanitation requirement set forth in Section 3 be found to exist, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three days have elapsed; the reinspection shall be used to determine compliance with sanitation requirements of Section 3. Any violation of the same sanitation requirement in Section 3 on such reinspection shall call for permit suspension in accordance with Section 5 (Permits).~~

~~**SECTION 7. The Examination of Imitation Milk, Imitation Milk Products and Products Made in Semblance of Milk and Milk Products.**~~

~~The examination of products defined in these regulations shall be conducted in accordance with the applicable standards and procedures contained in Section 6 of the Rules and Regulations Governing Milk and Milk Products, South Carolina Department of Health and Environmental Control, 1968, as amended.~~

~~**SECTION 8. Imitation Milk, Imitation Milk Products and Products Made in Semblance of Milk and Milk Products from Points Beyond the Limits of Routine Inspection.**~~

~~Products, defined in these regulations and processed and packaged outside the geographic limits of routine inspection of the South Carolina Department of Health and Environmental Control, or its police jurisdiction, may be sold in South Carolina, or its police jurisdiction, provided they are processed and packaged under routine official supervision, in compliance with standards, rules and regulations substantially equivalent to those applicable to like products processed and packaged in South Carolina.~~

~~**SECTION 9. Personnel Health.**~~

~~No person affected with any disease in a communicable form, or while a carrier of such disease, shall work at any plant or distribution station in any capacity which brings him in contact with the production, handling, storage, or transportation of products defined in these regulations, containers, equipment, or utensils; and no plant owner or manager shall employ in any such capacity any such person, or any person suspected of having any disease in a communicable form, or of being a carrier of such disease. Any plant owner or manager in whose plant any communicable disease occurs, or who suspects that any employee has contracted any disease in a communicable form, or has become a carrier of such disease, shall notify the Department of Health and Environmental Control.~~

~~**SECTION 10. Procedure When Infection is Suspected.**~~

~~When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of products defined in these regulations, the health authority is authorized to require any or all of the following measures:~~

~~1. The immediate exclusion of that person from product handling.~~

~~2. The immediate exclusion of the product concerned from distribution and use.~~

~~3. Adequate medical and bacteriological examination of the person, or his associates, and his and their body discharges.~~

~~**SECTION 11. Reference to Rules and Regulations Governing Milk and Milk Products.**~~

~~In addition to definitions and requirements contained in these regulations, all requirements contained in Rules and Regulations Governing Milk and Milk Products, South Carolina Department of Health and Environmental Control, 1968, as amended, which are applicable shall be required for the processing, storing, and offering for sale of imitation milk, imitation milk products, and products made in semblance of milk and milk products.~~

~~**SECTION 12. Enforcement.**~~

These regulations shall be enforced by the health authority, in accordance with interpretations and public health reasons approved by the South Carolina Department of Health and Environmental Control.

SECTION 13. Penalties.

Violations of these regulations shall be punishable in accordance with Section 44-1-150, Code of Laws of South Carolina, 1976, by fine not exceeding $100 or imprisonment not exceeding 30 days; and each day of continued violation shall be a separate offense.

SECTION 14. Repeal and Date of Effect.

These regulations shall be in full force and effect immediately after their adoption and publication; and, at that time all regulations and part of regulations in conflict with this regulation are hereby repealed.

SECTION 15. Unconstitutionality Clause.

Should any section, paragraph, sentence, clause, or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of said regulation shall not be affected thereby. [Repealed].

61-36. FROZEN DESSERTS.

(Statutory Authority: S.C. Code Ann. Sections 44-1-140 et seq., 44-1-140(11), 1-23-10, and 1-23-110 (1976, as amended))

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SECTION I. DEFINITIONS

The following definitions shall apply in the interpretation and the enforcement of this Regulation:

ADULTERATED FROZEN DESSERTS - a frozen dessert is deemed to be adulterated if the product:

1. Bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health;

~~2. Bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by State or Federal regulation, or in excess of such tolerance if one has been established;~~

~~3. Consists, in whole or in part, of any substance unfit for human consumption;~~

~~4. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;~~

~~5. Is packaged in a container which is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or~~

~~6. Has any substance added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.~~

~~7. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 342) will be considered as a violation of this Regulation.~~

~~AND/OR – "and" shall apply where appropriate, otherwise "or" shall apply.~~

~~ASEPTICALLY PROCESSED MIX – a frozen dessert mix that is hermetically sealed in a container and so thermally processed in conformance with 21 CFR 113 and the provisions of this Regulation so as to render the product free or microorganisms capable of reproducing in the product under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.~~

~~ASEPTIC PROCESSING – a process whereby the mix has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR 113 and the provisions of Section VII (B), Item 16, of this Regulation and maintain the commercial sterility of the product under normal non-refrigerated conditions.~~

~~DEPARTMENT – the authorized representative of the South Carolina Department of Health and Environmental Control.~~

~~DRUG – shall mean:~~

~~1. articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and~~

~~2. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and~~

~~3. articles (other than food) intended to affect the structure of any function of the body of man or other animals; and~~

~~4. articles intended for use as a component of any articles specified in clauses 1, 2, or 3, but does not include devices or their components, parts, or accessories.~~

~~FOUNTAIN FREEZER – a freezer which is installed and used for freezing frozen desserts which are held in the freezer under refrigeration until they are served for immediate consumption.~~

~~FROZEN DESSERTS – frozen desserts as used in this regulation shall be defined in S.C. Code Ann. Section 39-37-10 (1976, as amended). They shall also include mixes used for frozen dessert manufacturing~~

~~and products such as gelato and sorbetto made in semblance of those products defined in Section 39-37-10.~~

~~FROZEN DESSERTS MANUFACTURER - any person, except frozen dairy foods retailer, who manufactures, processes, or freezes any frozen desserts for distribution or sale.~~

~~FROZEN DESSERTS PLANT - any place or premises except frozen dairy foods retailers where frozen desserts are manufactured, processed, or frozen for distribution or sale.~~

~~FROZEN DESSERTS RETAILER - any person who sells, serves, dispenses or processes by fountain freezing, frozen desserts at retail which have been processed in an approved frozen desserts plant.~~

~~HERMETICALLY SEALED CONTAINER - a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.~~

~~MIX - the unfrozen combination of ingredients of frozen desserts except such fruits, nuts, flavors, color, and other ingredients as may be exempted by the Department. Mix shall be pasteurized.~~

~~NOVELTIES - Frozen desserts, either alone or in combination with other foods such as cookies, wafers, cones, coating, confections, etc., which are packaged in single-serving units.~~

~~PASTEURIZATION - the process of heating every particle of mix in properly designed and operated equipment to one of the temperatures given in the following table, and held continuously at or above that temperature for at least the corresponding specified time:~~

~~**TEMPERATURE / TIME**~~
~~155 degrees F / 30 Minutes~~
~~175 degrees F / 25 Seconds~~
~~180 degrees F / 15 Seconds~~
~~191 degrees F / 1.0 Second~~
~~194 degrees F / 0.5 Second~~
~~201 degrees F / 0.1 Second~~
~~204 degrees F / 0.05 Second~~
~~212 degrees F / 0.01 Second~~

~~Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the United States Food and Drug Administration (FDA) to be equally efficient and which is approved by the Department.~~

~~PERSON - any individual, plant operator, partnership, corporation, company, firm, trustee, association, or institution.~~

~~OFFICIALLY DESIGNATED LABORATORY - a commercial laboratory authorized to do official work by the Department, or a milk industry laboratory officially designated by the Department for the examination of producer samples of Grade A raw milk for pasteurization and commingled milk tank truck samples of raw milk for antibiotic residues and bacterial limits.~~

~~OFFICIAL LABORATORY - a biological, chemical, or physical laboratory which is under the direct supervision of the Department.~~

~~SANITIZATION - the application of any effective method or substance to a clean surface for the destruction of pathogens, and of other organisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product or the health of consumers, and shall be acceptable to the Department.~~

~~STERILIZED - the condition achieved by application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers free of viable microorganisms.~~

~~ULTRA-PASTEURIZED - mix that has been thermally processed at or above 138ºC (280ºF) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.~~

~~SECTION II. ADULTERATED OR MISBRANDED FROZEN DESSERTS~~

~~A. No person shall within the State of South Carolina, or its jurisdiction, produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell any frozen dessert which is adulterated or misbranded. Any frozen dessert which may contain any unwholesome substance, or which if defined in this Regulation does not conform with the definition, shall be deemed adulterated and/or misbranded.~~

~~B. Any adulterated or misbranded frozen dessert may be impounded by the Department and disposed of in accordance with applicable laws or regulations.~~

~~C. Frozen desserts shall be examined by the Department as often as may be necessary to determine freedom from adulteration or misbranding. The Department may, upon written notice to the owner or person in charge, place a hold order on any frozen dessert which it determines or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, frozen desserts shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice or tag placed on frozen desserts by the Department, and neither such frozen desserts nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the Department, except on order by a court of competent jurisdiction.~~

~~D. When frozen desserts are found to be adulterated by drugs, pesticides, herbicides, or other poisonous substances, the adulterated products shall be removed from the market, disposed of, and sale stopped until analysis provides the product to be free from adulteration.~~

~~SECTION III. COMPLIANCE PROCEDURES:~~

~~A. PERMIT:~~

~~1. It shall be unlawful for any person who does not possess a permit from the Department to bring into, send into, or receive into South Carolina or its jurisdiction, for sale, or to sell, or offer for sale therein, or to have in storage any frozen dessert defined in this Regulation: Provided, that grocery stores, restaurants, soda fountains, and similar establishments where frozen desserts are served or sold at retail, but not processed, other than fountain freezing of approved pasteurized mix, may be exempt from the requirements of this section.~~

~~2. Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain such a permit. Every frozen dessert manufacturer shall have a permit. Permits shall not be transferred with respect to persons and/or locations.~~

~~B. SUSPENSION OF PERMIT:~~

~~1. The Department shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this Regulation; or whenever the permit holder has interfered with the Department in the performance of its duties: Provided, that the Department shall, in all cases except where the frozen desserts involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the permit holder, manager or other duly authorized representative, a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in questions and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by the Department before making any order of suspension effective. A suspension shall remain in effect until the violation has been corrected to the satisfaction of the Department.~~

~~2. When the permit suspension is due to violations other than bacterial, coliform, cooling temperature standards or adulteration by drugs, the permit holder, manager or other duly authorized representative, is notified of the intent to suspend the permit in fifteen days unless a written request for a hearing is filed by the permit holder within such fifteen day period with the Department. If the hearing upholds the findings of the Department, the permit shall be suspended until the reasons for the suspension have been corrected.~~

~~3. The Department may without warning, notice, or hearing suspend a permit to operate a frozen dessert plant when it is determined that the operation of the frozen dessert plant constitutes an imminent health hazard, e.g., violations of bacterial, coliform, cooling temperatures, or adulteration by growth inhibitors (drugs) or other deleterious substances. Following immediate permit suspension, all manufacturing operations shall immediately cease. The Department shall promptly notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit was suspended, and that an opportunity for a hearing will be provided if a written request for a hearing is filed with the Department by the permit holder, manager or other duly authorized representative, within fifteen days. If no written request for a hearing is filed within fifteen days, the suspension is sustained. During the process, the permit shall remain suspended unless the imminent health hazard has been corrected.~~

~~4. Hearings on suspension of permits provided for in this section shall be conducted in accordance, where applicable, with the South Carolina Administrative Procedures Act, S.C. Code Ann. Section 1-23-310 et. seq., 1976, as amended) and applicable regulations.~~

~~5. Any frozen dessert or mix manufacturer whose permit has been suspended may make written application for the reinstatement of his permit.~~

~~6. Within one week of receiving the written application, the Department shall make inspections and/or collect samples for analysis to determine the applicant's establishment is in substantial compliance with this Regulation. If conditions warrant, the permit will be reinstated.~~

~~C. REVOCATION OF PERMIT:~~

~~1. The Department may revoke a permit after an opportunity for a hearing has been provided for repeated critical violations of any of the requirements of this regulation, or for interference with the Department of the performance of duty. Notwithstanding any other provisions of this regulation, the permit shall be revoked if the Department is threatened with bodily harm or physical interference in the performance of inspectional duties.~~

~~2. Prior to revocation, the Department shall notify, in writing, the permit holder, manager or other duly authorized representative, of the specific reasons for which the permit is to be revoked and that the permit~~

~~shall be revoked at the end of the fifteen days following service of such notice unless a written request for a hearing is filed with the Department by the permit holder, manager or other duly authorized representative, within such fifteen day period.~~

~~3. When a permit has been revoked, the holder of the revoked permit may make written application for a new permit; however, the Department may deny a new permit based upon past history.~~

~~4. The revocation of a permit, provided for in this chapter, shall be conducted in accordance with the South Carolina Administrative Procedures Act.~~

~~5. A notice provided for in this regulation is properly served when it is delivered to the permit holder, manager or other duly authorized representative, or when it is sent by registered or certified mail, return receipt requested and delivery restricted to the addressee, to the last known address of the frozen dessert plant's permit holder.~~

~~6. The hearings provided for in this regulation shall be conducted in accordance with the South Carolina Administrative Procedures Act, S.C. Code Ann. Section 1-23-310 et. seq. (1976, as amended). and applicable regulations.~~

~~SECTION IV. LABELING~~

~~All cans, packages, and other containers enclosing mix and frozen desserts or their ingredients derived from milk or edible food fats, except those filled from labeled bulk containers in retail dispensing, shall be plainly labeled or marked with: (1) the name of the contents; and (2) the name and address of the plant at which the contents were placed in the container. A frozen desserts manufacturing plant may be identified by a code when the Department is given advance notice of the coding. The label shall be in letters of an approved size, kind, and color and shall contain no marks or words which are misleading. All finished product labeling (name of product, ingredients, nutrition facts, net contents, etc.) shall conform to applicable federal and state labeling laws.~~

~~SECTION V. INSPECTION OF FROZEN DESSERT PLANTS:~~

~~A. Each frozen desserts manufacturer whose frozen desserts are intended for consumption within South Carolina or its jurisdiction shall be inspected by the Department prior to the issuance of a permit.~~

~~B. Following the issuance of a permit, the Department shall inspect each frozen dessert manufacturer at least once every three months.~~

~~C. If a violation of any requirement set forth in Section VI or Section VII is found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three days; this second inspection shall be used to determine compliance with the requirements of Section VI or VII. Any violation of the same requirement of Section VI or VII on such second inspection shall call for permit suspension in accordance with Section III and/or court action.~~

~~D. Provided, that when the Department finds that a critical processing element violation involving:~~

~~1. Proper pasteurization, whereby every particle of mix or frozen desserts may not have been heated to the proper temperature and held for the required time in properly designed and operating equipment; or~~

~~2. A cross connection exists whereby direct contamination of pasteurized mix or frozen dessert is occurring; or~~

~~3. Conditions exist whereby direct contamination of pasteurized mix or frozen desserts is occurring, the Department shall take immediate action to prevent further processing of such mix or frozen dessert until such violations of critical processing element(s) have been corrected. Should correction of such critical processing elements not be accomplished immediately, the Department shall take prompt action to suspend the permit as provided for in Section III of this Regulation.~~

~~E. Provided, that in the case of a mix plant producing aseptically processed mix, when an inspection of the mix plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to the public health and the Department shall take immediate action to suspend the permit of the plant for the sale of aseptically processed mix in conformance with Section III of this Regulation.~~

~~F. One copy of the inspection report shall be handed to the operator, or other responsible person, or be posted in a conspicuous place on an inside wall of the establishment. Said inspection report shall not be defaced and shall be made available to the Department upon request. An identical copy of the inspection report shall be filed with the records of the Department.~~

~~G. Every frozen desserts plant operator shall, upon request of the Department, permit access of officially designated persons to all parts of his establishment or facilities to determine compliance with the provisions of this Regulation. A plant operator shall furnish the Department, upon request, for official use only, a true statement of the actual quantities of frozen desserts purchased and sold, and a list of all sources of such frozen desserts, records of inspections, tests, and pasteurization time and temperature records.~~

~~H. It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this Regulation which is entitled to protection as a trade secret (including information as to the quantity, quality, source or disposition of frozen desserts, or results of inspections or tests thereof) to use such information to his own advantage or to reveal it to any unauthorized person.~~

~~SECTION VI. THE EXAMINATION OF FROZEN DESSERTS~~

~~A. SAMPLING CRITERIA:~~

~~1. During any consecutive six months, at least four samples of pasteurized mix and a variety of different flavors, types and sizes of containers of frozen desserts and frozen dessert novelties defined in this Regulation, except aseptically processed mix, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days, from every frozen desserts plant by the Department.~~

~~2. Samples of frozen desserts shall be taken while in the possession of the manufacturer and/or distributor at any time prior to delivery to the store or consumer.~~

~~3. Samples of frozen desserts from stores, cafes, soda fountains, restaurants, and other places where frozen desserts are sold may be examined as often as the Department may require.~~

~~B. SAMPLING ENFORCEMENT:~~

~~1. Whenever two of the last four consecutive bacterial counts (except those for aseptically processed mix), coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for frozen desserts, the Department shall send a certified or hand delivered written notice thereof to the person concerned. This notice shall be in effect so long as two of the last four consecutive samples~~

~~exceed the limit of the standard. An additional sample shall be taken within twenty-one days of the sending of such notice, but not before the lapse of three days. Immediate suspension of permit in accordance with Section III, and/or court action shall be instituted whenever the standard is violated by three of the last five bacterial counts (except those for aseptically processed mix), coliform determinations, or cooling temperatures.~~

~~2. Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any mix or frozen desserts involved shall not be offered for sale.~~

~~3. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no frozen desserts shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.~~

~~4. Whenever a drug residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provision of Section II of this Regulation.~~

~~5. Whenever a container or containers of aseptically processed mix is found to be unsterile due to underprocessing, the Department shall consider this to be an imminent hazard to public health and shall suspend the permit of the mix plant for the sale of aseptically processed mix. No aseptically processed mix or frozen desserts made from the mix, shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All products, including frozen desserts, manufactured from the lot found to contain one or more unsterile units shall be recalled and disposed of as directed by the Department.~~

~~C. SAMPLING METHODS:~~

~~Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the Standard Methods for the Examination of Dairy Products of the American Public Health Association, and the certification of sample collectors, and examinations shall be evaluated in accordance with the United States Public Health Service/FDA Evaluation of Milk Laboratories. Aseptically processed mix packaged in hermetically sealed containers shall be tested in accordance with the FDA's Bacteriological Analytical Manual. Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Department requires.~~

~~SECTION VII. FROZEN DESSERT PLANTS~~

~~A. TEMPERATURE, BACTERIOLOGICAL AND CHEMICAL REQUIREMENTS~~

~~1. All frozen desserts shall be produced, processed, and pasteurized, ultra-pasteurized, aseptically processed and frozen to conform with the following temperature, bacteriological, and chemical standards and the sanitation requirements of this section:~~

~~a. Raw Milk and Milk Products for Pasteurization, Ultra Pasteurization, and Aseptic Processing:~~

~~(1) Temperature – Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).~~

~~(2) Bacterial Limits - Individual producer milk not to exceed 100,000 per mL prior to commingling with other producer milk. Not to exceed 300,000 per mL as commingled milk prior to pasteurization.~~

~~(3) Somatic Cell Count - Individual producer milk not to exceed 750,000 per mL. Goat milk not to exceed 1,000,000 per mL.~~

~~(4) Drugs - No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques, FDA Grade A PMO as amended.~~

~~b. Pasteurized Frozen Desserts and Heat-Treated, Bulk-Shipped Milk Products:~~

~~(1) Temperature - Cooled to 7°C (45°F) or less and maintained thereat.~~

~~(2) Bacterial limits* - 30,000 per mL.~~

~~(3) Coliform - Not to exceed 10 per mL: provided that, in the case of bulk milk transport tank shipments, where contents are to be repasteurized, shall not exceed 100 per mL.~~

~~(4) Phosphatase** - Less than 500 milliunits/L by the Fluorometer or Clarion ALP or equivalent.~~

~~(5) Drugs - No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques, FDA Grade A PMO as amended.~~

~~c. Aseptically Processed Mix:~~

~~(1) Temperature - None.~~

~~(2) Bacterial limits - No growth by test specified in Section VI.~~

~~(3) Drugs - No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques, FDA Grade A PMO as amended.~~

~~*Not applicable to cultured products.~~
~~**Not applicable to bulk shipped heat-treated milk products.~~

~~2. No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing, freezing, processing methods integral therewith, and appropriate refrigeration (freezing) shall be applied to mix and frozen desserts for the purpose of removing or deactivating microorganisms: Provided, that in the bulk shipment of cream, skim milk, or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 125°F but less than 161°F for separation purposes is permitted when the resulting bulk shipments of cream, skim milk, and/or lowfat milk are labeled heat-treated.~~

~~B. SANITATION OF FROZEN DESSERT PLANTS~~

~~1. Floors - Construction: The floors of all rooms in which frozen desserts, or their ingredients are processed, handled or stored, including cold storage rooms, or in which containers, equipment and utensils are washed or stored shall be constructed of concrete or other equally impervious and easily cleaned material and shall be kept in good repair. Floors in all areas in which frozen desserts or their ingredients are processed or in which containers, equipment and utensils are washed shall be properly sloped and equipped with trapped drains.~~

~~2. Walls and Ceilings - Construction: Walls and ceilings of room in which frozen desserts or their ingredients are processed, handled, or stored, or in which containers, utensils, and equipment are washed shall have a smooth, water resistant, washable, light-colored surface in good repair.~~

~~3. Doors and Windows: Effective means shall be provided to prevent the access of insects and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather. Outside openings shall be protected against the entrance of insects by tight-fitting, self-closing doors, closed windows, screening, effective air curtains or other means.~~

~~4. Lighting and Ventilation:~~

~~a. All rooms in which frozen desserts or their ingredients are handled, processed, or stored, and/or in which containers, equipment, and utensils are washed shall be well lighted and ventilated. At least twenty foot candles of light are needed in working areas. Dry storage and cold storage rooms need at least five foot candles of light.~~

~~b. Pressurized ventilating systems shall have a filtered air intake.~~

~~5. Separate Rooms:~~

~~a. There shall be separate rooms for:~~

~~(1) The pasteurizing, processing, cooling, freezing and packaging of mix and frozen desserts.~~

~~(2) Cleaning and sanitizing facilities for tank trucks in plants receiving mix or milk products in such tanks.~~

~~(3) Receiving cans of mix in plants receiving such cans.~~

~~b. Rooms in which mix or frozen desserts are handled, processed, or stored, or in which containers, utensils, and equipment are washed or stored shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.~~

~~c. Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged mix and frozen desserts.~~

~~6. Toilet-Sewage Disposal Facilities:~~

~~Every frozen desserts plant shall be provided with toilet facilities conforming with state and local plumbing laws, regulations and codes. Toilet rooms shall not open directly into any room in which frozen desserts, their ingredients, equipment, or containers are processed, handled or stored. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in wastewater system approved by the Department. A sign directing employees to wash their hands before returning to work shall be posted in all toilet rooms used by employees.~~

~~7. Water Supply:~~

~~a. Water for frozen dessert plant purposes shall be from a supply properly located, protected and operated, and shall be easily accessible, adequate and of a safe, sanitary quality.~~

~~b. Samples for bacteriological testing of individual water supplies shall be taken by the Department upon the initial approval of the physical structure, each six months thereafter, and when any repair or alteration of the water supply system has been made. Examinations shall be conducted in an official laboratory, and records maintained.~~

~~8. Hand-washing Facilities: Convenient hand-washing facilities shall be provided, including hot and cold and/or warm running water, soap, and individual sanitary towels or approved hand-drying devices. Handwashing facilities shall be kept in a clean condition and in good repair.~~

~~9. Frozen Dessert Plant Cleanliness: All rooms in which frozen desserts are handled, processed, frozen or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or to handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, freezing, packaging and bulk milk product storage rooms.~~

~~10. Sanitary Piping:~~

~~a. All sanitary piping, fittings and connections which are exposed to frozen desserts, or from which liquids may drip, drain or be drawn into frozen desserts, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material. All piping shall be in good repair. Pasteurized frozen desserts shall be conducted from one piece of equipment to another only through sanitary piping.~~

~~b. All sanitary piping, connections and fittings shall consist of:~~

~~(1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or~~

~~(2) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or~~

~~(3) Heat resistant glass; or~~

~~(4) Plastic, or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat-resistant, relatively nonabsorbent, relatively insoluble, do not release component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications and for short flexible take down jumpers or connections where flexibility is required for essential or functional reasons.~~

~~11. Construction and Repair of Containers and Equipment:~~

~~a. All multi-use containers and equipment with which frozen desserts or their ingredients come into contact shall be smooth, impervious, corrosion-resistant, and of non-toxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets, and other articles with which frozen desserts come in contact shall be nontoxic and shall have been manufactured, packaged, transported and handled in a sanitary manner.~~

~~b. All frozen dessert contact surfaces of multi-use containers and equipment shall consist of:~~

~~(1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or~~

~~(2) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or~~

~~(3) Heat resistant glass; or~~

~~(4) Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, and do not release component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.~~

~~NOTE: 3-A Sanitary Standards for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection, and the Milk Safety Branch, Center for Food Safety and Applied Nutrition, United States Public Health Service/Food and Drug Administration, Department of Health and Human Services.~~

~~12. Cleaning and Sanitizing of Containers and Equipment:~~

~~a. The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, handling, freezing and storage of frozen desserts shall be effectively cleaned after each use, at least daily, and shall be sanitized before each use. Provided, that piping, equipment and containers used to process, conduct or package aseptically processed mix beyond the final heat treatment process shall be sterilized before any aseptically processed mix is packaged and shall be re-sterilized whenever any unsterile product has contaminated it.~~

~~b. Storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two hours, except that permission may be granted by the Department for storage of pasteurized mix longer than seventy-two hours, provided necessary plant quality controls are in place. Storage tanks which are used to store raw milk, mix or heat treated milk products longer than twenty-four hours shall be equipped with a seven-day temperature recording device.~~

~~c. A temperature recording device, complying with the specifications in Appendix H, FDA Grade A PMO as amended, or a recording device which has been reviewed by FDA and found to provide sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the Department shall be installed in the return solution or other appropriate areas to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions.~~

~~d. Recording charts shall be identified, dated and retained for three months. The Department shall review the recording charts during each inspection.~~

~~13. Storage of Cleaned Containers and Equipment: After cleaning, all multi-use frozen dessert containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.~~

~~14. Storage and Handling of Single-Service Containers, Utensils and Materials: Covers, caps, parchment papers, wrappers, can liners, and single-service sticks, spoons and containers for frozen desserts or their ingredients shall be purchased and stored only in sanitary containers; wrappings or cartons shall be kept therein in a clean, dry place until used, and shall be handled in a sanitary manner.~~

~~15. Protection from Contamination~~

~~a. Frozen dessert plant operations, equipment and facilities shall be located and conducted to prevent any contamination of frozen dessert products, ingredients, equipment, containers and utensils. All frozen desserts or ingredients which have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than mix or frozen desserts in the plant shall be performed to preclude the contamination of such frozen desserts. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of frozen desserts or ingredients of such frozen desserts or the product-contact surfaces of all equipment, containers or utensils.~~

~~b. Frozen desserts in broken and open containers may after delivery be returned to the plant for inspection but shall not be used for making frozen desserts.~~

~~c. Whenever air under pressure is used for the agitation or movement of frozen desserts or other ingredients, or is directed at frozen dessert contact surfaces or other ingredients, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix H, FDA Grade A PMO as amended. The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with frozen desserts, it shall be of culinary quality and shall comply with the applicable standards of Appendix H, FDA Grade A PMO as amended.~~

~~16. Pasteurization Aseptic Processing:~~

~~a. All mix shall be pasteurized or aseptically processed as described in Section I of this Regulation.~~

~~b. To insure that pasteurization temperature and time will be applied to every particle of mix, the system design, public health controls and testing shall comply with Section 7. Item 16p of the FDA Grade A PMO as amended.~~

~~17. Cooling:~~

~~a. All milk and fluid milk products received at frozen dessert plants for use in frozen desserts shall be cooled immediately in approved equipment to 45°F or less and maintained at that temperature until pasteurized. All pasteurized mix shall be cooled immediately in approved equipment to 45°F or less and maintained at that temperature until frozen.~~

~~b. All mix which is not frozen at the plant at which it was pasteurized shall be transported to the place of manufacturing or freezing in a sanitary manner and maintained at a temperature of 45°F or less until processed. Every room or tank in which milk products or mix are stored shall be equipped with an accurate thermometer, which shall comply with the specifications of Appendix H, FDA Grade A PMO as amended.~~

~~c. Recirculated cooling agents (water or glycol) which are used in coolers and exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such cooling agents shall be tested semiannually and shall comply with the bacteriological standards of Appendix G, FDA Grade A PMO as amended. Samples shall be taken by the Department and examination shall be conducted in an official laboratory. Recirculated water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants, and other chemical additives, when used in recirculating systems, shall be nontoxic under conditions of use.~~

~~18. Packaging:~~

~~a. Packaging, cutting, molding, dipping, and other preparation of frozen desserts or their ingredients shall be done in a sanitary manner using approved equipment.~~

~~b. Filling equipment for frozen desserts shall have drip defectors on the filler valve to prevent condensate from entering the product or container. Shielding shall be provided over conveyors for cartons, lids, caps and filled containers until they are closed to prevent water condensate or other contamination from entering the product.~~

~~c. The product contact surface of the container, including the pouring lip for mix containers, shall be covered by the closure/lid.~~

~~d. Hand capping/packaging is not an acceptable practice. Hand capping/packaging may be approved only if suitable mechanical equipment for the capping/packaging of specific containers is not available or is not practical for use. If hand capping is approved, a Department approved procedure will be established which will eliminate all possibility of contamination.~~

~~19. Ingredients~~

~~a. All raw milk and milk products used in the manufacture of frozen desserts shall be from a Grade A domestic source as defined in the FDA Grade A Pasteurized Milk Ordinance as amended or from other supplies acceptable to the Department. All mix and frozen dessert ingredients shall be clean, have a fresh wholesome flavor and odor and a normal appearance, be of satisfactory quality and shall be processed in an approved, sanitary manner.~~

~~b. The only ingredients which may be added after pasteurization are those flavoring and coloring ingredients which are:~~

~~(1) Subjected to prior heat treatment sufficient to destroy pathogenic microorganisms.~~

~~(2) Of 0.85% water activity or less,~~

~~(3) Of pH less than 4.7,~~

~~(4) Roasted nuts (added at the freezer),~~

~~(5) Contain high alcohol content,~~
~~(6) Bacterial cultures,~~

~~(7) Fruits and vegetables added at the freezer, or~~

~~(8) Subjected to any other process which will assure that the ingredient is free of pathogenic organisms.~~

~~20. Personnel - Cleanliness: Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. Employees shall not resume work after visiting the toilet room without thoroughly washing their hands. All persons while engaged in the processing, pasteurization, freezing, handling, storage or transportation of mix or frozen desserts, containers, equipment and utensils shall wear clean outer garments. All persons while engaged in the processing of mix and frozen desserts shall wear adequate hair covering and shall not use tobacco.~~

~~21. Vehicles: All vehicles used for the transportation of frozen desserts or their ingredients shall be so constructed and operated as to protect their contents from the sun and from contamination. Such vehicles shall be kept clean and no substance capable of contaminating mix or frozen desserts or their ingredients shall be transported therewith in such manner as to permit contamination. The name of the distributor shall be prominently displayed on the vehicles.~~

~~22. Surroundings:~~

~~a. Frozen dessert plants shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents, or otherwise constitute a nuisance.~~

~~b. Only insecticides and rodenticides approved for use by the Department and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.~~

~~SECTION VIII. FROZEN DESSERTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION~~

~~Frozen desserts from points beyond the limits of routine inspection by the Department may be sold in South Carolina if they are manufactured under provisions substantially equivalent to the requirements of this Regulation; provided, that the Department shall be satisfied that the agency having jurisdiction over the manufacture of these products is properly enforcing such provisions.~~

~~SECTION IX. PLANS FOR CONSTRUCTION AND RECONSTRUCTION~~

~~Properly prepared plans for all frozen dessert plants regulated under this Regulation which are hereafter constructed, reconstructed or extensively altered shall be submitted to the Department for written approval before work is begun.~~

~~SECTION X. PERSONNEL HEALTH~~

~~No person affected with any disease capable of being transmitted to others through the contamination of food shall work at any frozen desserts plant in any capacity which brings them into direct contact with finished products, such as pasteurized or aseptically processed mix or frozen desserts, or which brings them into direct contact with associated pasteurized or aseptically processed mix and frozen dessert product contact surfaces.~~

~~SECTION XI. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED:~~

~~When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of frozen desserts, or their ingredients, the Department is authorized to require any or all of the following measures:~~

~~A. The immediate exclusion of that person from handling frozen desserts, or their ingredients;~~

~~B. The immediate exclusion of the frozen desserts concerned from distribution and use;~~

~~C. Adequate medical and bacteriological examination of the person, of his associates, and of his and their body discharges.~~

~~SECTION XII. RECALLS~~

~~Each frozen desserts manufacturer should develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the operator or the Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the Department determines, based upon representative samples, risk analysis, information provided by the frozen desserts manufacturer, and other information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the frozen desserts manufacturer to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The frozen desserts manufacturer shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.~~

~~SECTION XIII. PENALTIES:~~

~~Violations of this regulation shall be punishable in accordance with S.C. Code Ann. Section 44-1-150 (1976 as amended). Each day of continued violation shall be a separate offense.~~

~~SECTION XIV. REPEAL AND DATE OF EFFECT:~~

~~All previous amendments of this regulation are hereby repealed; this regulation shall be in full force and effect immediately upon adoption and its publication, as provided by law.~~

~~SECTION XV. SEVERABILITY CLAUSE:~~

~~Should any section, paragraph, sentence, clause or phrase of this Regulation be declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.~~

61-36. MANUFACTURED GRADE DAIRY PRODUCTS.

Statutory Authority: S.C. Code Sections 44-1-140, 44-1-150, and 39-37-120

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SECTION I. DEFINITIONS

The following definitions shall apply in the interpretation and the enforcement of this regulation:

A. ADULTERATED - a manufactured grade dairy product is deemed to be ADULTERATED if the product:

1. Bears or contains any poisonous or deleterious substance in a quantity that may render it injurious to health;

2. Bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by state or federal regulation, or in excess of such tolerance if one has been established;

3. Consists, in whole or in part, of any substance unfit for human consumption;

4. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;

5. Is packaged in a container which is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

6. Has any substance added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;

7. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 342); or

8. Contains any animal DRUG residues.

B. ALCOHOL INFUSED FROZEN DESSERT- any frozen dessert that contains five percent (5%) or more alcohol by volume.

C. APPROVED - acceptable to the DEPARTMENT based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

D. ASEPTICALLY PROCESSED MIX - a manufactured grade dairy product that is hermetically sealed in a container and so thermally processed in conformance with 21 CFR Part 113 and the provisions of this regulation so as to render the product free of MICROORGANISMS capable of reproducing in the product

under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable MICROORGANISMS (including spores) of public health significance.

E. ASEPTIC PROCESSING - a process whereby the manufactured grade dairy product has been subjected to sufficient heat processing, and packaged in a HERMETICALLY SEALED CONTAINER, to conform to the applicable requirements of 21 CFR Part 113 and the provisions of Section VII A.1.c. of this regulation and maintain the commercial sterility of the product under normal non-refrigerated conditions.

F. BUSINESS DAY - every official work day of the week excluding weekends and state holidays.

G. BUTTER - the food product usually known as BUTTER that is made exclusively from MILK or cream, or both, with or without salt, and with or without additional coloring matter, and which contains not less than eighty percent (80%) by weight of MILK fat. BUTTER may contain: (a) MILK solids; (b) APPROVED bacterial culture; (c) salt; (d) air or inert gas; and (e) APPROVED food color. BUTTER also includes the following MANUFACTURED GRADE DAIRY PRODUCTS:

1. BUTTER WITH (NAMING THE FRUIT, VEGETABLE, OR RELISH) - BUTTER to which any fruit, vegetable, or relish, or any combination thereof, has been added. It may contain less than eighty percent (80%) MILK fat if the percentage of MILK fat is reduced by the amount of the product added, but the resulting MILK fat content must be at least seventy-five (75%).

2. BUTTER WITH (NAMING THE SEASONING OR FLAVOR) - BUTTER to which a seasoning or a flavor other than that of BUTTER, or both, has been added. It must contain at least eighty percent (80%) MILK fat.

3. CALORIE-REDUCED BUTTER - the food product usually known as calorie-reduced BUTTER that is prepared from MILK or MILK products or a combination thereof, and which contains at least thirty-nine (39%) MILK fat and not more than fifty percent (50%) of the calories that would normally be present in BUTTER. CALORIE-REDUCED BUTTER may contain: (a) MILK solids; (b) APPROVED bacterial culture; (c) salt; (d) air or inert gas; (e) APPROVED food color; (f) APPROVED emulsifying and stabilizing agents; (g) APPROVED preservatives; and (h) not more than one percent (1%) added edible casein, edible caseinates, or any combination thereof.

4. LIGHT BUTTER OR LITE BUTTER - food product usually known as LIGHT BUTTER or LITE BUTTER, which is prepared from MILK or MILK products or a combination thereof, and which contains at least thirty-nine (39%) MILK fat and not more than sixty percent (60%) MILK fat. LIGHT BUTTER or LITE BUTTER may contain: (a) MILK solids; (b) APPROVED bacterial culture; (c) salt; (d) air or inert gas; and (e) APPROVED food color.

5. WHEY BUTTER - food product usually known as WHEY BUTTER that is prepared from MILK or MILK products or a combination thereof, and which contains at least eighty percent (80%) MILK fat that is recovered from whey, by weight. WHEY BUTTER may contain: (a) MILK solids; (b) APPROVED bacterial culture; (c) salt; (d) air or inert gas; and (e) APPROVED food color.

H. CODE OF FEDERAL REGULATIONS (CFR) - a codification of the general and permanent rules and regulations (administrative LAW) published in the Federal Register by the executive departments and agencies of the federal government of the United States. Citations to the CFR in this regulation refer sequentially to the Title, Part, and Section numbers (e.g., 21 CFR 117.10 refers to Title 21, Part 117, Section 117.10).

I. CHEESE - the fresh or matured product obtained by draining after coagulation of MILK, cream, skimmed or partly skimmed MILK, or a combination of some or all of these products, including any CHEESE that conforms to the requirements of 21 CFR 133, as amended.

J. DEPARTMENT - the South Carolina Department of Health and Environmental Control and its authorized representatives.

K. DRUG - shall mean:

1. articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

2. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

3. articles (other than food) intended to affect the structure of any function of the body of man or other animals; and

4. articles intended for use as a component of any articles specified in clauses 1, 2, or 3, but does not include devices or their components, parts, or accessories.

L. EMPLOYEE - permit holder, PERSON in charge, PERSON having supervisory or managerial duties, PERSON on the payroll, family member, volunteer, PERSON performing work under a contractual agreement, or any other PERSON working in a MANUFACTURED GRADE DAIRY PRODUCTS plant or distribution station.

M. EXCLUSION - prevention of a PERSON from working as an EMPLOYEE in a MANUFACTURED GRADE DAIRY PRODUCTS plant or distribution station or entering a MANUFACTURED GRADE DAIRY PRODUCTS plant or distribution station as an EMPLOYEE.

N. FDA - United States Food and Drug Administration.

O. FD&C - United States Food, Drug, and Cosmetic Act, the federal LAWS giving authority to FDA to oversee the safety of food, DRUGS, medical devices and cosmetics, as set forth in 21 U.S.C. Section 301 et seq.

P. FOOD - means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C) and includes raw materials and ingredients.

Q. FROZEN DESSERTS - as used in this regulation is defined in S.C. Code Ann. Section 39-37-10. They shall also include MIXES used for frozen dessert manufacturing and products such as gelato and sorbetto made in semblance of those products defined in Section 39-37-10.

R. HERMETICALLY SEALED CONTAINER - a container that is designed and intended to be secure against the entry of MICROORGANISMS and thereby maintain the commercial sterility of its contents after processing.

S. IMITATION MILK AND IMITATION MILK PRODUCTS, SYNTHETIC MILK AND SYNTHETIC MILK PRODUCTS, MILK DERIVATIVES, AND ANY OTHER PRODUCTS MADE IN SEMBLANCE OF MILK OR MILK PRODUCTS - Products made in semblance of MILK and MILK products are products that are made to resemble in form and are intended to be used in substitution for

MILK and/or MILK products and that are determined not to be nutritionally inferior to MILK and/or MILK products.

T. IMMINENT HEALTH HAZARD - a significant threat or danger to health that is considered to exist when there is sufficient evidence to show that a product, practice, circumstance, or event creates a situation requiring immediate correction or cessation of operation to prevent illness or injury based on the number of potential illnesses or injuries, and the nature, severity, and duration of the anticipated illness or injury.

U. LAW - applicable local, state, and federal statues, regulations, and ordinances.

V. MANUFACTURED GRADE DAIRY PRODUCT(S) - refers to all types of CHEESES, BUTTERS, FROZEN DESSERTS (including MIX), and IMITATION MILK and IMITATION MILK PRODUCTS, SYNTHETIC MILK AND SYNTHETIC MILK PRODUCTS, MILK DERIVATIVES, and ANY OTHER PRODUCTS MADE IN SEMBLANCE OF MILK OR MILK PRODUCTS.

W. MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION - any place or PREMISES, except MANUFACTURED GRADE DAIRY PRODUCTS RETAILERS, where MANUFACTURED GRADE DAIRY PRODUCTS are received, stored, and dispensed to retailers (may also be referred to as “Distribution Station”).

X. MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR - any PERSON, except a MANUFACTURED GRADE DAIRY PRODUCTS RETAILER, who receives, stores, and dispenses MANUFACTURED GRADE DAIRY PRODUCTS to retailers (may also be referred to as “Distributor”).

Y. MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER - any PERSON, except a MANUFACTURED GRADE DAIRY PRODUCTS RETAILER, who manufactures, processes, or freezes MANUFACTURED GRADE DAIRY PRODUCTS for distribution or sale.

Z. MANUFACTURED GRADE DAIRY PRODUCTS PLANT - any place or PREMISES, except MANUFACTURED GRADE DAIRY PRODUCTS RETAILERS, where MANUFACTURED GRADE DAIRY PRODUCTS are manufactured, processed, or frozen for distribution or sale.

AA. MANUFACTURED GRADE DAIRY PRODUCTS RETAILER - any PERSON who sells, serves, or dispenses MANUFACTURED GRADE DAIRY PRODUCTS at retail which have been processed in an APPROVED MANUFACTURED GRADE DAIRY PRODUCTS PLANT.

BB. MICROORGANISMS - means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable MICROORGANISMS" includes those MICROORGANISMS that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be ADULTERATED.

CC. MILK (HOOVED MAMMALS’ MILK) - Hooved mammals’ MILK is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. Hooved mammals for the purpose of this regulation include, but are not limited to, the members of the Order Cetartiodactyla, such as: Family Bovidae (cattle, water buffalo, sheep, goats, yaks, etc.), Family Camelidae (llamas, alpacas, camels, etc.), Family Cervidae (deer, reindeer, moose, etc.), and Family Equidae (horses, donkeys, etc.).

DD. MIX - the unfrozen combination of ingredients of FROZEN DESSERTS except such fruits, nuts, flavors, color, and other ingredients as may be exempted by the DEPARTMENT. MIX shall be pasteurized.

EE. NUISANCE - for purposes of this regulation, a public health NUISANCE, meaning whatever is dangerous to human life or detrimental to health; or whatever structure or PREMISES is not sufficiently ventilated, sewered, drained, cleaned, or lighted with respect to its intended occupancy.

FF. OFFICIALLY DESIGNATED LABORATORY - a commercial laboratory authorized to do official work by the DEPARTMENT, or a MILK industry laboratory officially designated by the DEPARTMENT for the examination of producer samples of Grade "A" RAW MILK for PASTEURIZATION and commingled MILK tank truck samples of RAW MILK for antibiotic residues and bacterial limits.

GG. OFFICIAL LABORATORY - a biological, chemical, or physical laboratory that is under the direct supervision of the DEPARTMENT.

HH. PASTEURIZATION - the process of heating every particle of manufactured grade dairy product in properly designed and operated equipment to one of the temperatures given in the following table, and holding the product continuously at or above that temperature for at least the corresponding specified time:

Batch (Vat) Pasteurization	
Temperature	**Time**
145°F (63°C)*	30 minutes
Continuous Flow (HTST and HHST) Pasteurization	
Temperature	**Time**
161°F (72°C)*	15 seconds
191°F (89°C)	1.0 second
194°F (90°C)	0.5 second
201°F (94°C)	0.1 second
204°F (96°C)	0.05 second
212°F (100°C)	0.01 second

*If the fat content of the dairy product is ten percent (10%) or greater, or a total solids of eighteen percent (18%) or greater, or if it contains added sweeteners, the specified temperature shall be increased by 5°F (3°C).

Provided, that FROZEN DESSERTS shall be heated to at least the following temperature and time specifications:

Batch (Vat) Pasteurization	
Temperature	**Time**
155°F (69°C)	30 minutes
Continuous Flow (HTST) Pasteurization	
Temperature	**Time**
175°F (80°C)	25 seconds
180°F (83°C)	15 seconds

Provided, that MILK for CHEESE making shall be heated to at least the following temperature and time specification:

Batch (Vat) Pasteurization	
Temperature	**Time**
145°F (63°C)	30 minutes
Continuous Flow (HTST) Pasteurization	
Temperature	**Time**
161°F (72°C)	15 seconds

Provided, that cream for BUTTER making shall be heated to at least the following temperature and time specifications:

Batch (Vat) Pasteurization	
Temperature	**Time**
165°F (74°C)	30 minutes
Continuous Flow (HTST) Pasteurization	
Temperature	**Time**
185°F (85°C)	15 seconds

Provided further that nothing in this definition shall be construed as barring any other process found equivalent to PASTEURIZATION for dairy products, which has been recognized by the FDA as provided in Section 403(h)(3) of the FD&C (21 U.S.C. Section 343(h)(3)), as amended, and which is APPROVED by the DEPARTMENT.

II. PATHOGEN - a microorganism of public health significance.

JJ. PERMIT - the document issued by the DEPARTMENT that authorizes a PERSON or entity to operate a MANUFACTURED GRADE DAIRY PRODUCTS PLANT or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION.

KK. PERMIT HOLDER - the entity, such as the owner, the owner's agent, or other PERSON, that possesses a valid PERMIT to operate a MANUFACTURED GRADE DAIRY PRODUCTS PLANT or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION and is legally responsible for its operation.

LL. PERSON - any individual, plant operator, partnership, corporation, company, firm, trustee, association, or institution.

MM. PEST - any objectionable animals or insects including but not limited to birds, rodents, flies, and larvae.

NN. PASTEURIZED MILK ORDINANCE (PMO) - a set of minimum standards and requirements that are established by the FDA for regulating the production, processing, and packaging of Grade "A" MILK.

OO. PREMISES -

1. The physical facility, its contents, its land, and any adjacent or bordering contiguous land or property under the control of the PERMIT HOLDER; or

2. The physical facility, its contents, and land or property not described in (a) of this definition if the facilities and contents are under the control of the PERMIT HOLDER and may impact the MANUFACTURED GRADE DAIRY PRODUCTS PLANT or distribution station personnel, facilities, or operations, and the MANUFACTURED GRADE DAIRY PRODUCTS PLANT or distribution station is only one component of a larger operation such as a healthcare facility, hotel, motel, school, recreational camp, or prison.

PP. RAW MILK - MILK that has not been pasteurized.

QQ. RESTRICTION - limitation of the activities of an EMPLOYEE so that there is no risk of transmitting a disease that is transmissible through MANUFACTURED GRADE DAIRY PRODUCTS or ingredients and the EMPLOYEE does not work with exposed MANUFACTURED GRADE DAIRY PRODUCTS or ingredients, clean equipment, utensils, linens, or unwrapped single-service or single-use articles.

RR. RETAIL FOOD ESTABLISHMENT - an establishment that sells food products directly to consumers as its primary function. Retail food establishments include, but are not limited to, grocery stores, convenience stores, roadside stands, farmers markets, and community supported agriculture (CSA) operations. Any business making food (including a farm business) with at least 50.1 percent in direct to individual consumer food sales satisfies the definition of a RETAIL FOOD ESTABLISHMENT and is exempt from the Bioterrorism Act registration regulations under the 2002 Bioterrorism Act (21 CODE OF FEDERAL REGULATIONS [C.F.R.] 1.225) as a retail food establishment. The term “consumers” does not include businesses. A RETAIL FOOD ESTABLISHMENT also includes certain farm-operated businesses selling food directly to consumers as their primary function.

SS. RISK - the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

TT. SANITIZE - to adequately treat cleaned surfaces by a DEPARTMENT-accepted process that is effective in destroying vegetative cells of PATHOGENS, and in substantially reducing numbers of other undesirable MICROORGANISMS, but without adversely affecting the product or its safety for the consumer.

UU. ULTRA-PASTEURIZED - manufactured grade dairy product that has been thermally processed at or above 280ºF (138ºC) for at least two (2) seconds, either before or after packaging, so as to produce a product that has an extended shelf life under refrigerated conditions.

VV. UNEXPOSED PACKAGED FOOD - packaged food that is not exposed to the environment.

Additional definitions related to this regulation are found in 21 CFR 117.3, as amended.

SECTION II. ADULTERATED OR MISBRANDED MANUFACTURED GRADE DAIRY PRODUCTS

A. No PERSON within South Carolina, or its jurisdiction, shall produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell, any manufactured grade dairy product that is ADULTERATED or misbranded. Any manufactured grade dairy product that may contain any unwholesome substance, or that does not conform with an applicable standard of identity or other requirement under Section I for that particular manufactured grade dairy product, shall be deemed ADULTERATED and/or misbranded.

B. The DEPARTMENT issues PERMITS for the manufacturing of ALCOHOL INFUSED FROZEN DESSERTS. The DEPARTMENT does not regulate the distribution or sale of ALCOHOL INFUSED FROZEN DESSERTS. Compliance with DEPARTMENT requirements under this regulation does not exempt PERSONS engaged in the production, distribution, or sale of ALCOHOL INFUSED FROZEN DESSERTS from any other applicable LAWS governing the sale or distribution of alcoholic products.

C. The DEPARTMENT may place a hold order on a manufactured grade dairy product that it determines or has reason to believe:

1. Originated from an unapproved source;

2. May be unsafe, unwholesome, ADULTERATED, misbranded, or not honestly presented;

3. Is not labeled according to LAW; or

4. Is otherwise not in compliance with this regulation.

D. The DEPARTMENT may suspend a PERSON'S PERMIT for violating a hold order.

E. The DEPARTMENT may impound, condemn, forbid the sale of, or cause to be removed or destroyed, any food that is determined to be in violation of this regulation, unwholesome, contaminated, ADULTERATED, misbranded, or from an unapproved source.

F. The DEPARTMENT may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the food, as specified above, without prior warning, notice of a hearing, or a hearing on the hold order.

G. The DEPARTMENT may examine MANUFACTURED GRADE DAIRY PRODUCTS as often as necessary to determine freedom from adulteration or misbranding. Under a hold order, MANUFACTURED GRADE DAIRY PRODUCTS shall be suitably stored. It shall be unlawful for any PERSON to remove or alter a hold order, notice, or tag placed on MANUFACTURED GRADE DAIRY PRODUCTS by the DEPARTMENT, and neither such MANUFACTURED GRADE DAIRY PRODUCTS nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the DEPARTMENT, except on order by a court of competent jurisdiction.

H. Whenever MANUFACTURED GRADE DAIRY PRODUCTS are ADULTERATED by DRUGS, pesticides, herbicides, or other poisonous substances, the PERSON or entity in possession of the product shall remove the product from the market, dispose of the product, and stop sale of the product until analysis provides the product to be free from adulteration.

SECTION III. COMPLIANCE PROCEDURES

A. PERMIT.

1. It shall be unlawful for any PERSON to manufacture or distribute any MANUFACTURED GRADE DAIRY PRODUCT without a valid PERMIT issued by the DEPARTMENT for the specific MANUFCTURED GRADE DAIRY PRODUCTS PLANT or DISTRIBUTION STATION. Grocery stores, restaurants, and similar establishments where MANUFACTURED GRADE DAIRY PRODUCTS are served or sold at retail, but not processed (other than fountain freezing of APPROVED pasteurized MIX for FROZEN DESSERTS), may be exempt from the requirements of this section.

2. Every MANUFACTURED GRADE DAIRY PRODUCTS PLANT and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION must obtain a PERMIT. PERMITS are nontransferable with respect to PERSONS and/or locations.

B. Suspension of PERMIT.

1. The DEPARTMENT may suspend a PERMIT whenever:

a. it has reason to believe that a public health hazard exists;

b. the PERMIT HOLDER has violated any of the requirements of this regulation;

c. the PERMIT HOLDER has violated its PERMIT or an order of the DEPARTMENT, including but not limited to, a hold order; or

d. the PERMIT HOLDER has interfered with the DEPARTMENT in the performance of its duties.

A suspension shall remain in effect until the violation has been corrected to the satisfaction of the DEPARTMENT.

2. The DEPARTMENT may without prior warning or notice, suspend summarily a PERMIT to operate a MANUFACTURED GRADE DAIRY PRODUCTS PLANT or DISTRIBUTION STATION when the DEPARTMENT determines that the operation of the MANUFACTURED GRADE DAIRY PRODUCTS PLANT or DISTRIBUTION STATION, including but not limited to a willful refusal to permit authorized inspection, constitutes an IMMINENT HEALTH HAZARD. Upon summary PERMIT suspension, all manufacturing and distribution operations shall immediately cease. During the process, the permit shall remain suspended unless the IMMINENT HEALTH HAZARD has been corrected.

3. Any MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR whose PERMIT has been suspended may make written application for the reinstatement of the PERMIT.

4. Within seven (7) BUSINESS DAYS of receiving the written application, the DEPARTMENT shall make inspections and/or collect samples for analysis to determine whether the conditions cited in the notice of suspension no longer exist. If conditions warrant, the DEPARTMENT may reinstate the PERMIT.

C. Revocation of PERMIT.

1. The DEPARTMENT may revoke a PERMIT for repeated violations of any of the requirements of this regulation, the PERMIT, or an order of the DEPARTMENT, or for interference with the DEPARTMENT or its staff in the performance of its duties. Notwithstanding any other provisions of this regulation, the PERMIT may be revoked if the DEPARTMENT is threatened with bodily harm or physical interference in the performance of inspectional duties.

2. The DEPARTMENT may deny a new PERMIT based upon past noncompliance, including previous enforcement, suspension, or revocation history.

3. Any PERSON whose PERMIT is revoked shall not be eligible to apply for repermitting within one (1) year from the date of revocation. Any PERSON whose PERMIT has previously been revoked and who

obtains a subsequent PERMIT and violates the provisions of this regulation, resulting in revocation of the PERMIT for a second time, shall not be granted another PERMIT for a period of five (5) years.

SECTION IV. LABELING

MANUFACTURED GRADE DAIRY PRODUCTS must be labeled according to the requirements in 21 CFR Part 101, as amended.

SECTION V. INSPECTION OF MANUFACTURED GRADE DAIRY PRODUCTS PLANTS, AND MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS

A. Each MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER whose MANUFACTURED GRADE DAIRY PRODUCTS are intended for consumption within South Carolina or its jurisdiction shall be inspected by the DEPARTMENT prior to the issuance of a PERMIT.

B. Following the issuance of a PERMIT, the DEPARTMENT will inspect each MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and DISTRIBUTOR at a frequency determined by the RISK level assigned to the product(s) being manufactured or distributed, or as otherwise deemed necessary by the DEPARTMENT to determine compliance with this regulation.

C. When the DEPARTMENT finds a critical processing element violation involving:

1. Improper PASTEURIZATION, whereby every particle of a manufactured grade dairy product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment; or

2. cross contamination whereby direct contamination of a pasteurized manufactured grade dairy product is occurring; or

3. conditions whereby direct contamination of a manufactured grade dairy product is occurring,
the DEPARTMENT shall take immediate action to prevent further processing of such MIX or manufactured grade dairy product until all violations of critical processing element(s) have been corrected. Should correction of such critical processing elements not be accomplished immediately, the DEPARTMENT will take prompt action to suspend the PERMIT as provided for in Section III of this regulation.

D. In the case of a plant producing ASEPTICALLY PROCESSED MIX, when an inspection of the plant or its records reveal that the process used has been less than the required scheduled process, as per the PMO, it shall be considered an IMMINENT HEALTH HAZARD and the DEPARTMENT shall take immediate action to suspend the PERMIT of the plant for the sale of aseptically processed MANUFACTURED GRADE DAIRY PRODUCTS in conformance with Section III of this regulation.

E. A copy of the inspection report will be provided either electronically or in paper form to the PERMIT HOLDER, manager, or other duly authorized representative.

F. Every MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and DISTRIBUTOR shall, upon request of a DEPARTMENT representative, permit the DEPARTM,ENT access to all parts of the establishment or facilities to determine compliance with the provisions of this regulation. A PERMIT HOLDER, manager, or other duly authorized representative shall furnish the DEPARTMENT, upon request and for official use only, a true statement of the actual quantities of manufactured grade dairy product purchased and sold, and a list of all sources of such manufactured grade dairy product, records of inspections, records of tests, and PASTEURIZATION time and temperature records.

G. It is unlawful for any PERSON who, in an official capacity, obtains any information under the provisions of this regulation which is entitled to protection as a trade secret, to use such information to his or her own advantage or to reveal it to any unauthorized PERSON.

SECTION VI. THE EXAMINATION OF MANUFACTURED GRADE DAIRY PRODUCTS

A. Sampling criteria.

1. Samples of MANUFACTURED GRADE DAIRY PRODUCTS shall be collected by the manufacturer or the DEPARTMENT, as directed, at a frequency that is deemed appropriate by the DEPARTMENT based on the level of RISK of the product.

2. Samples may be taken while in the possession of the manufacturer and/or distributor, retail stores, cafes, restaurants, and other places where MANUFACTURED GRADE DAIRY PRODUCTS are sold and shall be taken and examined as often as the DEPARTMENT may require.

B. Sampling enforcement.

1. Upon receipt of unsatisfactory samples, as specified in (a) and (b) below, the DEPARTMENT shall send a written notice thereof to the PERMIT HOLDER of the MANUFACTURED GRADE DAIRY PRODUCTS PLANT or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION.

a. For FROZEN DESSERTS this notice shall be sent when two (2) of the last four (4) consecutive bacterial counts (except those for ASEPTICALLY PROCESSED MIX), coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for FROZEN DESSERTS. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. The DEPARTMENT shall suspend the manufacturer and/or distributor's PERMIT in accordance with Section III and/or take court action as necessary whenever the additional sampling results indicate that three (3) of the last five (5) bacterial counts (except those for ASEPTICALLY PROCESSED MIX), coliform determinations, or cooling temperatures exceed the limit of the standard for FROZEN DESSERTS.

b. For CHEESE and BUTTER, this notice shall be sent when a sample is confirmed to be positive for pathogenic organisms. A positive finding of pathogenic organisms in a sample shall be considered an IMMINENT HEALTH HAZARD, and the product involved shall not be offered for sale. The DEPARTMENT shall immediately suspend the PERMIT and the PERMIT shall remain suspended until a minimum of two (2) consecutive representative samples are found to be free of pathogenic organisms.

2. Whenever a phosphatase test is positive, the cause shall be determined by the PERMIT HOLDER. Where the cause is improper PASTEURIZATION, it shall be corrected, and any manufactured grade dairy product involved shall not be offered for sale.

3. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the product involved shall not be offered for sale. The cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no manufactured grade dairy product shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

4. Whenever a DRUG residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provision of Section II of this regulation.

5. Whenever a container or containers of aseptically processed manufactured grade dairy product is found to be unsterile due to under processing, the DEPARTMENT shall consider this to be an imminent hazard to public health and shall suspend the PERMIT of the manufactured grade dairy product plant for the sale of ASEPTICALLY PROCESSED manufactured grade dairy product. No ASEPTICALLY PROCESSED manufactured grade dairy product shall be sold until it can be shown that the processes, equipment, and procedures used are suitable for consistent production of a sterile product. All products, including manufactured grade dairy product, manufactured in or from the lot found to contain one (1) or more unsterile units shall be recalled and disposed of as directed by the DEPARTMENT.

C. Sampling methods.

Samples shall be analyzed at an official or appropriate OFFICIALLY DESIGNATED LABORATORY. All sampling procedures and required laboratory examinations shall be in substantial compliance with the Standard Methods for the Examination of Dairy Products of the American Public Health Association, and the certification of sample collectors, and examinations shall be evaluated in accordance with the United States Public Health Service/FDA Evaluation of MILK Laboratories. Aseptically processed MANUFACTURED GRADE DAIRY PRODUCTS packaged in HERMETICALLY SEALED CONTAINERS shall be tested in accordance with the FDA's Bacteriological Analytical Manual. Examinations and tests to detect adulterants, including pesticides, shall be conducted as the DEPARTMENT requires.

SECTION VII. STANDARDS FOR MANUFACTURED GRADE DAIRY PRODUCTS PLANTS AND MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS

A. Temperature, bacteriological and chemical requirements.

1. All frozen dessert MIX shall be produced, processed, and pasteurized, ULTRA-PASTEURIZED, or aseptically processed as specified in the PMO and frozen to conform with the following temperature, bacteriological, and chemical standards and the sanitation requirements of this section:

a. RAW MILK and milk products obtained by a frozen dessert manufacturer for future PASTEURIZATION, ULTRA-PASTEURIZATION, or ASEPTIC PROCESSING and use in the production of FROZEN DESSERTS must come from an APPROVED source and must be in compliance with the temperature, bacteriological, and chemical standards in R.61-34, Raw Milk for Human Consumption, or R. 61-34.1, Pasteurized Milk and Milk Products, or the PMO.

b. Pasteurized FROZEN DESSERTS and/or Heat-Treated, Bulk-Shipped Milk Products:

(1) Temperature – Cooled to 45°F (7°C) or less and maintained thereat.

(2) Bacterial limits* - 30,000 per mL.

(3) Coliform - Not to exceed 10 per mL: provided that, in the case of bulk MILK transport tank shipments, where contents are to be repasteurized, shall not exceed 100 per mL.

(4) Phosphatase** - Less than 500 milliunits/L by the Fluorometer or Clarion ALP or equivalent.

(5) DRUGS - No positive results on DRUG residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade "A" PMO as amended.

c. ASEPTICALLY PROCESSED MIX:

(1) Temperature - None.

(2) Bacterial limits - No growth by test specified in Section VI.

(3) DRUGS - No positive results on DRUG residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade "A" PMO as amended.

*Not applicable to cultured products.

**Not applicable to bulk shipped heat-treated products.

2. Each type of CHEESE shall conform to the sanitation requirements of this section and be produced and processed and pasteurized, ULTRA-PASTEURIZED, and aseptically processed to conform with the temperature, bacteriological, and chemical standards that are outlined below:

a. Except as provided in paragraph A.2.b. below, all MILK and MILK products used in the production of CHEESE shall meet the requirements in either (1) or (2) below:

(1) Be pasteurized or subjected to equivalent heat treatment by the CHEESE manufacturer in accordance with the applicable specifications under the definition of PASTEURIZATION in Section I of this regulation.

a. PASTEURIZATION achieved by methods other than those described in the current PMO must be achieved in accordance with a written procedure that has been APPROVED by the DEPARTMENT; and

b. has been proven by a phosphatase test to achieve PASTEURIZATION.

(2) Be made from pasteurized MILK products or from MILK products which have been subjected to equivalent heat treatment as outlined in Section I of this regulation.

b. If made from RAW MILK (CHEESE labeled as "heat treated", "unpasteurized", "RAW MILK", or "for manufacturing"), CHEESE must be aged for no less than sixty (60) days at a temperature greater than or equal to 35°F (1.7°C) in order to control microbial PATHOGENS.

c. RAW MILK and MILK products obtained by a CHEESE manufacturer for future PASTEURIZATION, ULTRA-PASTEURIZATION, or ASEPTIC PROCESSING and use in the production of CHEESE must come from an APPROVED source and be in compliance with the temperature, bacteriological, and chemical standards in R.61-34, Raw Milk for Human Consumption, or R. 61-34.1, Pasteurized Milk and Milk Products., or the PMO.

d. All CHEESE shall be made from ingredients that conform to the quality specifications for raw materials outlined in 21 CFR 58.430 through 58.437, as amended.

e. Each type of CHEESE must meet the specific standards and limits applicable to it under Subpart B of 21 CFR Part 133, as amended.

3. All BUTTERS shall conform to the sanitation requirements of 21 CFR 117.80 and be produced, processed, and pasteurized, ULTRA-PASTEURIZED, or aseptically processed to conform with the temperature, bacteriological, and chemical standards that are outlined below:

a. All BUTTERS shall be manufactured from MILK or MILK products that have been pasteurized or subjected to equivalent heat treatment in accordance with the applicable specifications under the definition of PASTEURIZATION in Section I of this regulation and shall not be made from RAW MILK or RAW MILK products.

(1) PASTEURIZATION achieved by methods other than those described in the current PMO must be achieved in accordance with a written procedure that has been APPROVED by the DEPARTMENT; and

(2) has been proven by a phosphatase test to achieve PASTEURIZATION.

b. All BUTTERS shall be made from ingredients that conform to the quality specifications for raw materials outlined in 7 CFR 58.322 through 58.331, as amended.

c. BUTTER specifications:

(1) Proteolytic count - Not more than 100 per gram.

(2) Yeast and mold count - Not more than 20 per gram.

(3) Coliform count - Not more than 10 per gram.

(4) Enterococci - Not more than 10 per gram.

4. No process or manipulation other than PASTEURIZATION, ULTRA-PASTEURIZATION or ASEPTIC PROCESSING, freezing, processing methods integral therewith, and appropriate refrigeration (freezing) shall be applied to MANUFACTURED GRADE DAIRY PRODUCTS for the purpose of removing or deactivating MICROORGANISMS.

5. All IMITATION MILK, IMITATION MILK PRODUCTS, AND PRODUCTS MADE IN SEMBLANCE OF MILK AND MILK PRODUCTS shall meet the minimum standards for the MILK or MILK product which it imitates or resembles, including those for fat and solids not fat. To each quart of IMITATION MILK, imitation low-fat MILK, imitation skim MILK, and products made in semblance of these products, 400 U.S.P. units of Vitamin D and 2000 U.S.P. units of Vitamin A shall be added.

B. Post- PASTEURIZATION ingredients.

Only the following flavoring ingredients and other ingredients which have been found to be safe and suitable may be added to a manufactured grade dairy product after PASTEURIZATION:

1. Fresh fruits and vegetables, provided the resultant equilibrium pH level (4.6 or below when measured at 75°F (24°C)) of the finished product is reached without undue delay and is maintained during the shelf life of the product;

2. Ingredients subjected to prior heating or other technology that has been demonstrated to the FDA to be sufficient to destroy or remove pathogenic MICROORGANISMS;

3. Ingredients having a water activity of 0.85% or less;

4. Ingredients having a high acid content (pH level of 4.6 or below when measured at 75°F (24°C)) or high alkalinity (pH level greater than 11 when measured at 75°F (24°C));

5. Roasted nuts;

6. Dry sugars and salts;

7. Safe and suitable bacterial cultures and enzymes;

8. Alcohol;

9. Ingredients that have been found to be safe and suitable by the FDA.

All such additions shall be made in a sanitary manner that prevents the contamination of the added ingredient or the manufactured grade dairy product.

C. Sanitation of MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS.

1. All MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURERS and DISTRIBUTORS, regardless of exemption status, shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, as amended.

a. In addition to the requirements in Section VII(C)(1) above, BUTTER plants, BUTTER manufacturers, BUTTER distribution stations, and BUTTER distributors shall comply with 7 CFR 58.311 through 58.321, as amended, and 7 CFR 58.332 through 58.344, as amended.

b. In addition to the requirements in Section, VII(C)(1) above, CHEESE plants, CHEESE manufacturers, CHEESE distribution stations, and CHEESE distributors shall comply with 7 CFR 58.406 through 58.429, as amended, and 7 CFR 58.438 through 58.445, as amended.

2. MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and DISTRIBUTION STATIONS that have been granted a Qualified Facility Exemption by the FDA or that are solely engaged in the storage of refrigerated UNEXPOSED PACKAGED FOODS when temperature controls are necessary to prevent PATHOGEN growth shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart D - Modified Requirements, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, and be familiar with Subpart E - Withdrawal of a Qualified Facility Exemption, as amended.

3. All MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and DISTRIBUTION STATIONS that have not been granted a Qualified Facility Exemption by the FDA shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart C - Hazard Analysis and Risk-Based Preventive Controls, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, as amended.

4. MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and DISTRIBUTION STATIONS that are requiring a withdrawal of their Qualified Facility Exemption from the FDA shall be subject to the requirements of 21 CFR Part 117, Subpart E - Withdrawal of a Qualified Facility Exemption, as amended.

5. Manufactured grade dairy plants and distribution stations that have not been granted a Qualified Facility Exemption by the FDA and have identified a hazard requiring a supply-chain applied control shall comply with the requirements of 21 CFR Part 117, Subpart G - Supply-Chain Program, as amended.

6. There shall be separate rooms for processing and packaging of different types of MANUFACTURED GRADE DAIRY PRODUCTS as determined by the DEPARTMENT.

7. Water Supply.

a. Water used for MANUFACTURED GRADE DAIRY PRODUCTS PLANT purposes shall be from a supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality. Any water used as an ingredient must be obtained from an APPROVED public water system as defined in R.61-58. Water for manufactured grade dairy plants that have not been granted a Qualified Facility Exemption by the FDA must be from an APPROVED public water supply.

b. Firms that have been granted a Qualified Facility Exemption by the FDA shall have their water supply tested. Samples for bacteriological testing of individual water supplies may be taken by the DEPARTMENT or by other APPROVED individuals with the results to be submitted to the DEPARTMENT upon the initial approval of the physical structure, annually thereafter, and when any repair or alteration of the water supply system has been made. Examinations shall be conducted in an OFFICIAL LABORATORY at the manufactured grade dairy product plant's expense. The plant must maintain records of the tested samples.

SECTION VIII. MANUFACTURED GRADE DAIRY PRODUCTS FROM OUT OF STATE OR OUTSIDE THE UNITED STATES

MANUFACTURED GRADE DAIRY PRODUCTS from out of state or outside the United States may be sold in South Carolina only if the DEPARTMENT determines they are manufactured and distributed under provisions substantially equivalent to the requirements of this regulation and adequately enforced.

SECTION IX. PLANS FOR CONSTRUCTION AND RECONSTRUCTION

Properly prepared plans for all MANUFACTURED GRADE DAIRY PRODUCTS PLANTS or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS regulated under this regulation which are to be constructed, reconstructed, or extensively altered shall be submitted to the DEPARTMENT for written approval before work is begun.

SECTION X. EQUIPMENT AND FACILITES IN OPERATION PRIOR TO JULY 1, 2020

Equipment and physical facilities of MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS in operation prior to July 1, 2020 are deemed in compliance even if they do not meet all construction, equipment, and facilities requirements of this regulation if the facilities and equipment:

A. Are in compliance with the regulatory standards in place for such equipment and facilities on January 1, 2020;

B. Are capable of being maintained in a sanitary condition;

C. Are not a public health hazard or NUISANCE; and

D. Are replaced in the normal course of operation with equipment and facilities that meet the requirements of this regulation.

This section shall not apply to equipment installed or construction commenced on or after July 1, 2020.

SECTION XI. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED

When reasonable cause exists to suspect the possibility of transmission of infection from any PERSON concerned with the handling of MANUFACTURED GRADE DAIRY PRODUCTS, or their ingredients, the DEPARTMENT is authorized to require any or all of the following measures:

A. The immediate EXCLUSION of that PERSON from handling MANUFACTURED GRADE DAIRY PRODUCTS, or their ingredients;

B. The immediate EXCLUSION of the MANUFACTURED GRADE DAIRY PRODUCTS of concern from distribution and use; and/or

C. Adequate medical and bacteriological examination of the PERSON, of their associates, and any of their bodily discharges.

SECTION XII. RECALLS

For MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURERS and DISTRIBUTORS that have not been granted a Qualified Facility Exemption by the FDA, the Recall Plan requirements of 21 CFR 117.139 supersede the requirements of this section.

If 21 CFR 117.139 does not apply, each MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the PERMIT HOLDER or the DEPARTMENT has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the DEPARTMENT determines, based upon representative samples, RISK analysis, information provided by the MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and/or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR, and/or other information available to the DEPARTMENT, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the DEPARTMENT may order the MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and/or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR to initiate a level of product recall or, if appropriate, issue a form of notification to customers. Each MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION XIII. ENFORCEMENT AND PENALTIES

Any PERSON found to be in violation of this regulation, in non-compliance with the issued PERMIT, or in violation of an order issued by the DEPARTMENT shall be subject to civil monetary penalties, PERMIT suspension, and/or PERMIT revocation. Each day of continued violation shall be a separate offense.

SECTION XIV. SEVERABILITY CLAUSE

Should any section, paragraph, sentence, clause, or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-140(3) and 44-1-150

Notice of Drafting:

The Department of Health and Environmental Control ("Department" or "DHEC") proposes amending R.61-36, Frozen Desserts. The Department further proposes amending the requirements of R.61-35, Imitation Milk, Imitation Milk Products, and Products Made in Semblance of Milk and Milk Products, and merging it into R.61-36. This will entail repealing R.61-35 and adding its amended requirements to R.61-36. Along with merging these regulations, the Department proposes adding regulatory requirements for manufacturing cheese, butter, and other non-grade "A" milk products to R.61-36 and changing its title.

Interested persons may submit written comments to Sandra D. Craig, Director, Division of Food and Lead Risk Assessments, Bureau of Environmental Health Services, S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201, or by email at craigsd@dhec.sc.gov. To be considered, written comments must be received no later than 5:00 p.m. on May 28, 2019, the close of the drafting comment period.

Synopsis:

The Department proposes amending R.61-36 and the requirements of R.61-35. Currently, R.61-36 and R.61-35 are both based on federal regulations found in the Code of Federal Regulations ("CFR"), 21 CFR Part 110, which was replaced with 21 CFR Part 117 on September 1, 2018. The Department proposes amending R.61-36 and R.61-35 to incorporate the requirements of 21 CFR Part 117. In the interest of efficiency, the Department proposes repealing R.61-35 and merging its amended requirements into R.61-36. The Department further proposes adding requirements for manufacturing cheese, butter, and other non-grade "A" milk products to R.61-36 and renaming the regulation R.61-36, Manufactured Grade Dairy Products. The South Carolina Department of Agriculture previously regulated cheese and butter products (also based on 21 CFR Part 110); however, oversight now resides with DHEC. The Department also proposes amendments not required by federal law, including updates from the current Pasteurized Milk Ordinance ("PMO") and additions, updates, and clarifications to administrative requirements, enforcement requirements, and definitions.

The Department may also propose stylistic changes such as corrections for clarity and readability, grammar, punctuation, references, codification, and overall improvement of the text of the regulation.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments and repeal, as portions of the above-referenced proposed amendments include updates or other changes to R.61-35 and R.61-36 that are not addressed by the federal regulations.

(x) ACTION/DECISION
( ) INFORMATION

Date: September 12, 2019

To: S.C. Board of Health and Environmental Control

From: Office of Budgets and Financial Planning

Re: Notice of Proposed Regulation Repealing R.61-1, Medical and Dental Scholarship Fund.

I. Introduction

The Office of Budgets and Financial Planning proposes the attached Notice of Proposed Regulation repealing R.61-1, *Medical and Dental Scholarship Fund* for publication in the September 27, 2019, *South Carolina State Register* ("*State Register*"). Legal authority resides in S.C. Code Sections 59-111-510 through 59-111-580, which established and outlines how the program was to be managed through the Department of Health and Environmental Control ("Department"). The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of this repeal.

II. Facts

1. S.C. Code Sections 59-111-510 through 59-111-580 established a Medical and Dental Scholarship Fund to be administered by the Department. Pursuant to S.C. Code Section 59-111-580, the Department promulgated R.61-1 to administer the program. In 1985, the General Assembly amended the statute to eliminate references to scholarships, leaving the program as only a loan fund, revised certain program criteria, and made other changes to the program. The regulation was never revised to conform to the amended statute.

2. The General Assembly last funded the program in the 1988 Appropriations Act for the 1988-1989 fiscal year. The last recipients completed their service obligations in 1996 following three years of residency and four years of service. In 1998 Act No. 419,Part II §5A Code of Laws Title 59 Education Chapter 123, the Medical University of South Carolina (MUSC) Section 59-123-125 stated: "The funds appropriated to the Medical University of South Carolina for the Rural Physician Program Shall be administered by the South Carolina Area Health Education Consortium (SCAHEC) Physician Recruitment Office."

Also, DHEC's Regulation 61-1 does not appear to be consistent with the statute as the regulation provides for scholarships and loans, and the statute provides just for loans. The General Assembly has not funded the Medical and Dental Scholarship/Loan Program since FY 1989. Upon reviewing both the statue and the regulation the Department believes that should the General Assembly provide funding, loans could be provided without a regulation because the promulgation of regulations is discretionary under the statue. As such, the Department proposes repealing R. 61-1.

3. The Department had a Notice of Drafting published in the March 22, 2019, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received no public comments by the April 22, 2019, close of the public comment period.

4. Appropriate Department staff conducted an internal review of the proposed repeal on August 7,2019.

5. A phone call and an email was sent to the SCAHEC Executive Director Ann Lefebrve, MSW, CPHQ to inform the organization of the proposed drafting and the rationale for the repeal.

"The Department of Health and Environmental Control is pursuing the repeal of Regulation 61-1 Medical and Dental Scholarship Fund. As such, I am reaching out to SCAHEC to make you aware and to answer any questions or concerns your organization may have.

The Department is seeking repeal for the following reasons:

- The General Assembly last funded the DHEC's program in the 1989 Appropriations Act. The last recipients completed their service obligations in 1996.
- In 1998 Act 419 Section 59-123-125 stated "The funds appropriated to the Medical University of South Carolina for the Rural Physician Program shall be administered by the South Carolina Area Health Education Consortium (SCAHEC) Physician Recruitment Office". It also created a board with the Commissioner or his designee of DHEC (currently Mark Jordan) as a member.
- DHEC's Regulation 61-1 does not appear to be consistent with the statute as the regulation provides for scholarships and loans, and the statute provides just for loan.
- Upon reviewing both the statue and the regulation the Department believes that should the General Assembly provide funding, loans could be provided without a regulation because the promulgation of regulations is discretionary under the statue."

III. Request for Approval

The Office of Budgets and Financial Planning respectfully requests the Board to grant approval of the attached Notice of Proposed Regulation for publication in the September 27, 2019, *State Register*.

Bruce C. Busbee
Office Director

Darbi C. MacPhail
Finance and Operations Director

Attachments:
A. Notice of Proposed Regulation
B. Notice of Drafting published in the March 22, 2019, *State Register*

ATTACHMENT A

STATE REGISTER NOTICE OF PROPOSED REGULATION
FOR R.61-1, Medical and Dental Scholarship Fund

September 12, 2019

Document No. _____
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 59-111-510 through 59-111-580

61-1. Medical and Dental Scholarship Fund.

Preamble:

The Department of Health and Environmental Control ("Department") proposes repealing R.61-1, which implements a Medical and Dental Scholarship/Loan Fund established by S.C. Code Sections 59-111-510 through 59-111-580. The Fund was intended to provide financial assistance for medical and dental school educations to recipients who would agree to practice in a rural area of the state for a specified period of time. The fund had originally been a scholarship program when the regulation was first adopted but was converted by statute to a loan fund in 1985; however, the regulation was never amended to conform to the amended statute. The General Assembly last funded the program in the 1988 Appropriations Act for the 1988-1989 fiscal year. The last recipients completed their service obligations in1996 following three years of residency and four years of service.

In 1989, when the S.C. General Assembly ceased to fund the Medical and Dental Loan Fund, it established a Rural Physician Program to address the undersupply of clinicians in rural and underserved South Carolina communities. The new program is administered by the South Carolina Area Health Education Consortium and fiscally managed by the Medical University of South Carolina. The program provides incentive grants for primary care physicians and advanced practice professionals who commit to practice in a rural or underserved area of South Carolina for a period of four years. Per S.C. Code Section 59-123-125, the Department's only current involvement with this fund extends to the SC DHEC Commissioner/Director or designee serving on the Rural Physician Board. Mark Jordan, Director of DHEC's Office of Primary Care, has served in this capacity since 1998.

The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of this repeal.

The Department had a Notice of Drafting published in the March 22, 2019, South Carolina State Register.

Section-by-Section Discussion of Proposed Repeal:

R.61-1 is struck in its entirety.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons may submit comment(s) on the proposed repeal to Bruce C. Busbee of the Office of Budgets and Financial Planning; S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201; Busbeebc@dhec.sc.gov. To be considered, the Department must receive the

comment(s) by 5:00 p.m. on October 28, 2019, the close of the comment period.

The S.C. Board of Health and Environmental Control will conduct a public hearing on the proposed repeal during its December 12, 2019, 10:00 a.m. meeting. Interested persons may make oral and/or submit written comments at the public hearing. Persons making oral comments should limit their statements to five (5) minutes or less. The meeting will take place in the Board Room of the DHEC Building, located at 2600 Bull Street, Columbia, S.C. 29201. Due to admittance procedures, all visitors must enter through the main Bull Street entrance and register at the front desk. The Department will publish a meeting agenda twenty-four (24) hours in advance indicating the order of its scheduled items at: http://www.scdhec.gov/Agency/docs/AGENDA.PDF.

The Department publishes a Monthly Regulation Development Update tracking the status of its proposed new regulations, amendments, and repeals and providing links to associated State Register documents at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/.

Preliminary Fiscal Impact Statement

No fiscal impact to the agency.

Statement of Need and Reasonableness

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: 61-1, Medical and Dental Scholarship Fund

Purpose: R.61-1 is no longer needed because when the S.C. General Assembly ceased to fund the Medical and Dental Loan Fund, it established a Rural Physician Program to address the undersupply of clinicians in rural and underserved South Carolina communities. The new program is administered by the South Carolina Area Health Education Consortium and fiscally managed by the Medical University of South Carolina .
Should the General Assembly decide to fund the Medical and Dental Fund the statue provides for funding loans without the need for regulation.

Legal Authority: 1976 Code Sections 59-111-510 through 59-111-580

Plan for Implementation: The DHEC Regulation Development Update (accessible at http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/) provides a summary of and link to this proposed repeal. Additionally, printed copies are available for a fee from the Department's Freedom of Information Office. Upon taking legal effect, Department personnel will take appropriate steps to inform the regulated community of the repeal and any associated information.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

DETERMINATION OF COSTS AND BENEFITS:

There are no costs to the state or its political subdivisions associated with the repeal of R.61-1. The benefit of repealing this regulation is removing an unnecessary regulation that is no longer consistent with the statute.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Repealing R.61-1 will have no effect on the environment and public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

Repealing R.61-1 will have no detrimental effect on the environment and public health.

Statement of Rationale:

The fund had originally been a scholarship program when the regulation was first adopted but was converted by statute to a loan fund in 1985; however, the regulation was never amended to conform to the amended statute. The General Assembly last funded the program in the 1988 Appropriations Act for the 1988-1989 fiscal year. The last recipients completed their service obligations in1996 following three years of residency and four years of service. In 1989, when the S.C. General Assembly ceased to fund the Medical and Dental Loan Fund, it established a Rural Physician Program to address the undersupply of clinicians in rural and underserved South Carolina communities. The new program is administered by the South Carolina Area Health Education Consortium and fiscally managed by the Medical University of South Carolina.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

~~61-1. Medical and Dental Scholarship Fund.~~

~~1. Public Notice: As soon as the initial appropriation to the Fund is approved by the Governor, and at appropriate intervals (at least annually) thereafter, the Office of Communications of the Department of Health and Environmental Control shall send a news release to all news media in South Carolina and nearby communities describing the availability of scholarship funds, the persons eligible, the contractual obligations to be assumed by successful applicants, and the address for application forms and information.~~

~~2. Assignment of Responsibility in Department: The Commissioner shall designate an office in the Department to be responsible for distribution of application forms approved by the Board, for collection of completed forms, and for performing other staff functions related to the operation of the Fund.~~

~~3. Deadline for Receipt of Applications: The Board may set from time to time appropriate dates after which no more applications will be accepted for a particular granting period. In order that all applicants be given equal consideration, such deadlines will allow adequate time for processing the applications prior to final selection of successful applicants by the Board.~~

~~4. Legal Residency in South Carolina: South Carolina residency shall be established in accordance with the principles of Section 59-101-70, S.C. Code, as amended, which currently provides in part as follows: "Persons who have been domiciled in South Carolina for a period no less than twelve months with an intention of making a permanent home therein, including persons in their majority, emancipated minors and unemancipated minors whose parents have been domiciled in this State for no less than twelve months with an intention of making a permanent home herein may be considered South Carolina residents, provided that where the parents of an unemancipated minor are living apart or are separated, divorced, or deceased, the residency of the child shall be determined by the place of domicile of the parent or legal guardian with whom the child normally resides. Students making application for residency status shall have the burden of proving that these requirements are met."~~

~~5. Investigation of Fitness of Applicants: The office designated in paragraph 2 shall make a careful and full investigation of the ability, character and qualifications of each applicant to determine his fitness. The office shall submit a written summary of its findings on each applicant to the Board through the Commissioner. This investigation shall include a sharing of information pertaining to the applicant with the medical or dental school(s) which has accepted him for enrollment and a visit to his home community contacting his family, his church, his school, his credit references, law enforcement authorities, and other knowledgeable persons. Each applicant shall be required to sign a release form authorizing any person or agency having information about his ability, character and qualifications to release such information to the Board or its agents.~~

~~6. Appearance before Board: The Board may examine each applicant to assist in determining if he is qualified.~~

~~7. Duration of Loan or Scholarship: Each loan or scholarship shall be for a period of one year. However, recipients of a loan or scholarship who successfully complete the related year of study shall have first priority on unobligated funds for renewal of the loan or scholarship for the succeeding year.~~

~~8. Amount of Loan or Scholarship: Each loan or scholarship shall consist of two parts: (1) Payment of tuition and other school related expenses up to a total of $5000 per year, and (2) an allowance of $100 per month for living expenses.~~

~~9. Practice Selection: Each loan or scholarship shall be based upon the condition that on or before six months from the date the applicant completes one year of internship he engage in the general practice of medicine or dentistry in a county within the State which has a doctor ratio of not more than one doctor for each two thousand people or a dentist ratio of not more than one dentist for each four thousand people. The Department shall keep a list of the counties having such ratios and the applicant may choose which of these counties he desires to practice in.~~

~~10. Determination of Doctor and Dentist Ratios: The number of doctors and dentists practicing in counties shall be primarily based on the latest data from the State Board of Medical Examiners and the State Board of Dentistry pertaining to practitioners licensed and registered by these Boards. The Board of Health and Environmental Control may also take into consideration the Federal physicians assigned in the counties inasmuch as the people they serve are included in the population of the counties. The population used in calculating the ratios shall be the estimate of the Research and Statistical Services Division of the Budget and Control Board closest to the time of assembly of the information from which the number of professionals is derived.~~

~~11. Repayment of Loan or Scholarship: For each year during which an applicant benefits from a loan or scholarship he shall be required to engage in practice as defined in paragraph 9 for one year. Such work shall in addition constitute a repayment of the loan or scholarship. Applicants who receive a scholarship or loan for four years shall only be required to practice in such a county for three years, at the end of which time the loan shall be considered paid in full. Where the Board is convinced that there is justifiable cause which the applicant could not have foreseen, the Board may allow him to repay the loan or scholarship by paying in cash the full amount of the loan or scholarship, plus 7% interest per year compounded semiannually.~~

~~12. Contracts with Applicants: Before being granted a loan or scholarship, each applicant shall enter into a contract with the Board, agreeing to the terms and conditions upon which the loan or scholarship shall be granted to him. The contract shall include terms and provisions to carry out the purpose and intent of paragraphs 7 through 10 and 14 of these regulations. It shall be signed by the chairman of the Board, countersigned by the executive secretary of the Board, and signed by the applicant.~~

~~13. Contracts with Professional Schools: The Board may make arrangements and execute contracts with approved medical or dental schools for the admission of students granted loans or scholarships by the Board. Such contracts may provide for the payment of tuition and other school related expenses directly to the schools. The Board, upon proper notice, may cancel any contract made with such institutions.~~

~~14. Failure of Recipient to Fulfill Contract: If the recipient of a scholarship fails without justifiable cause to practice medicine or dentistry in accordance with the terms of his contract, three times the entire amount of the scholarship benefits received, plus 7% interest per year compounded semiannually shall become due and payable. However, if the Board determines there is justifiable cause for the failure to practice pursuant~~

~~to the terms of the contract, it may relieve the recipient of the obligation to practice according to the terms of the contract, and shall provide for repayment of the amount received, plus 7% interest per year on any terms it may deem proper. Upon recommendation and request of the Board, the Attorney General shall institute proceedings for the purpose of recovering any amount due the State upon breach of the contract.~~

~~15. Receipts and Expenditures: Funds appropriated and all sums received in repayment of loans and scholarships shall be placed in the State Treasury to the credit of the South Carolina Medical and Dental Scholarship Fund. Loan and scholarship payments shall be paid out of this fund upon a voucher to the State Comptroller General signed by the chairman and the executive secretary of the Board.~~[Repealed].

ATTACHMENT B

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 59-111-510 through 59-111-580
Notice of Drafting:
The Department of Health and Environmental Control ("Department") proposes repealing R.61-1, Medical and Dental Scholarship Fund. Interested persons may submit comment(s) on this proposed repeal to Bruce C. Busbee of the Office of Budgets and Financial Planning; S.C. Department of Health and Environmental Control, 301 Gervais Street, Columbia, S.C. 29201; Busbeebc@dhec.sc.gov. To be considered, the Department must receive comments no later than 5:00 p.m. on April 22, 2019, the close of the draft comment period.
Synopsis:
South Carolina Code Sections 59-111-510 through 59-111-580 establish a Medical and Dental Loan Fund to be administered by the Department. The fund had originally been a scholarship program but was converted to a loan fund in 1985. Pursuant to Code Section 59-111-580, the Department adopted Regulation 61-1 to administer the program.
The General Assembly last funded the program in the 1988 Appropriations Act for the 1988-1989 fiscal year. The last recipients completed their service obligations in 1996 following three years of residency and four years of service.
Since the General Assembly has not funded the Medical and Dental Scholarship/Loan program since FY 1989, the Department has had no funds to administer and the program has been dormant for the past thirty years. The Department now proposes repealing R.61-1.
The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of this proposed repeal.
Since, the General Assembly has not funded the Medical and Dental Scholarship/Loan program since FY 1989, the Department has had no funds to administer and the program has been dormant for the past thirty years. The Department now proposes repealing R.61-1.
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