SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

March 11, 2021

( ) ACTION/DECISION
(X) INFORMATION

I. **TITLE:** Healthcare Quality Administrative and Consent Orders.

II. **SUBJECT:** Healthcare Quality Administrative Orders and Consent Orders for the period of January 1, 2021 through January 31, 2021.

III. **FACTS:** For the period of January 1, 2021 through January 31, 2021, Healthcare Quality reports five (5) Consent Orders totaling $21,600 in assessed monetary penalties and sixty-five (65) Notices of Violation and Civil Penalty totaling $18,850 in assessed monetary penalties. No Administrative Orders were executed during the reporting period.

Name of Bureau	Facility, Service, Provider, or Equipment Type	Notices of Violation and Civil Penalty	Administrative Orders	Consent Orders	Assessed Penalties
Bureau of Facilities Oversight	Community Residential Care Facility	47	0	0	$13,950
	Renal Dialysis Facility	0	0	1	$5,000
	Intermediate Care Facility for Individuals with Intellectual Disabilities	0	0	1	$5,700
	Nursing Home	18	0	0	$4,900
Bureau of Radiological Health	Radioactive Material Medical Facility	0	0	1	$7,500
	Dental X-Ray Facility	0	0	2	$3,400
TOTAL		**65**	**0**	**5**	**$40,450**

Submitted By:

Gwendolyn C. Thompson

Gwen C. Thompson
Deputy Director
Healthcare Quality

HEALTHCARE QUALITY ENFORCEMENT REPORT
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

March 11, 2021

Bureau of Facilities Oversight

1. Facilities in Violation of Public Health Order No. COVID-19-5

Violations: The Department found that the forty-seven (47) community residential care facilities (CRCFs) and eighteen (18) nursing homes listed below failed to submit a weekly visitation report to the Department by the mandatory deadline. Failure to submit the report by the deadline is in violation of the Department's October 7, 2020, Public Health Order that requires all nursing homes and community residential care facilities (CRCFs) licensed by the Department to submit a weekly report on their visitation status.

Enforcement Action: In January 2020, the Department issued Notices of Violation and Civil Penalty against forty-seven (47) community residential care facilities (CRCFs) and eighteen (18) nursing homes. All of the facilities listed below were required to pay the full amount of their accumulated penalties within twenty (20) days of the dated notices.

Facility Name	Facility Type	Civil Penalty	Payment Received
Arboretum at the Woodlands at Furman	CRCF	$250	No
B & J Residential Care Facility	CRCF	$250	Yes
Bell's Professional Residential Care Home	CRCF	$350	Yes
Blake at Edgewater	CRCF	$250	Yes
Brookstone Terrace of Woodruff	CRCF	$350	Yes
BTU Rest Home	CRCF	$350	Yes
Care with Love	CRCF	$350	Yes
Care with Love II	CRCF	$350	Yes
Carolina Gardens at York	CRCF	$250	No
Carriage House of Senior Living of Sumter	CRCF	$250	Yes
Carson's Community Care	CRCF	$350	Yes
Clarke House	CRCF	$250	Yes
Clemson Heritage	CRCF	$250	Yes
Easy Living	CRCF	$350	Yes
First Choice Home Care Facility	CRCF	$250	Yes
Gracelynn Residential Care Facility	CRCF	$450	Yes
Gene's Residential Care Facility	CRCF	$250	Yes
Harmony House Residential Care	CRCF	$450	No
Jessamine Community Residence	CRCF	$250	Yes
Lakeview Assisted Living	CRCF	$350	Yes
Lemonaide House	CRCF	$350	No
Lighthouse Residential Care Facility	CRCF	$350	Yes
Maria's Priority Care Residential Home II-B	CRCF	$250	Yes

Facility Name	Facility Type	Civil Penalty	Payment Received
Maria's Priority Care Residential Home II-F	CRCF	$250	Yes
Maryville Community Residence	CRCF	$250	Yes
Midland Park Residential Home Care	CRCF	$250	Yes
Miller Place Residential Care	CRCF	$250	No
Morningside of Georgetown	CRCF	$250	No
Morningside of Lancaster	CRCF	$250	Yes
Myrtle Beach Manor Retirement Community	CRCF	$250	No
Oakridge Community Care Home #1	CRCF	$250	Yes
Oasis Residential Home	CRCF	$250	Yes
Oliver's Care Home	CRCF	$250	Yes
Padd-Wren Home	CRCF	$250	Yes
Piedmont Pathways Community Residential Care Facility	CRCF	$250	No
Rumph's Residential Care	CRCF	$250	Yes
Serenity Manor of Holly Hill	CRCF	$250	Yes
Shem Creek Health Center	CRCF	$250	Yes
Summit Place of Anderson	CRCF	$250	Yes
Varnville Community Residence	CRCF	$450	Yes
Village Inn Community Care Home	CRCF	$450	No
We Care Residential	CRCF	$250	No
Wesley Commons Assisted Living & Special Care House	CRCF	$250	Yes
Wesleyan Suites	CRCF	$350	Yes
Westminster Towers Residential	CRCF	$250	Yes
Whitney Place	CRCF	$350	Yes
Williams Community Care Home	CRCF	$250	Yes
Arboretum at the Woodlands	Nursing Home	$250	Yes
Blue Ridge in Georgetown	Nursing Home	$250	No
Commander Nursing Center	Nursing Home	$250	Yes
Golden Age Operations	Nursing Home	$250	Yes
Heritage Home of Florence	Nursing Home	$250	Yes
Inman Operations	Nursing Home	$250	Yes
Iva Rehabilitation and Healthcare Center	Nursing Home	$250	Yes
Lexington Medical Center Extended Care	Nursing Home	$250	Yes
Loris Rehab and Nursing Center	Nursing Home	$250	Yes
Magnolia Manor - Greenwood	Nursing Home	$350	Yes
Methodist Manor Healthcare Center	Nursing Home	$350	Yes
Myrtle Beach Manor	Nursing Home	$250	No
NHC Healthcare Laurens	Nursing Home	$250	No
Patewood Rehabilitation and Healthcare Center	Nursing Home	$250	Yes
PruittHealth – Bamberg	Nursing Home	$250	Yes
PruittHealth – Rock Hill	Nursing Home	$350	No
Shem Creek Nursing and Rehab	Nursing Home	$250	Yes
Sumter East Health and Rehabilitation Center	Nursing Home	$350	Yes

Facility Type	Total # of Licensed Facilities	Total # of Licensed Stations
Renal Dialysis Facility	167	6,649

2. Sheriff Al Cannon Detention Center – Charleston, SC

Inspections and Investigations: The Department conducted a complaint investigation in November 2020 and discovered that the facility was in violation of statutory and regulatory standards.

Violations: The Department found the facility failed to comply with both the State Certification of Need and Health Facility Licensure Act and Regulation 61-97, *Standards for Licensing Renal Dialysis Facilities*, by operating an unlicensed renal dialysis facility in its infirmary.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of five thousand dollars ($5,000) against the facility. The facility was required to pay the full amount of the penalty within thirty (30) days of executing the Consent Order. The Department will process the facility's application for licensure as a renal dialysis facility upon receipt of the agreed-upon monetary penalty.

Remedial Action: The facility has made the required payment and the Department has approved the facility's application for licensure as a renal dialysis facility.

Prior Enforcement Actions: None in the past five years.

Facility Type	Total # of Licensed Facilities	Total # of Licensed Beds
Intermediate Care Facility for Individuals with Intellectual Disabilities	66	1,632

3. Whitten Center-Campus – Clinton, SC

Inspections and Investigations: The Department conducted multiple inspections and investigations in 2019 and 2020; and discovered that the facility had repeated multiple regulatory violations.

Violations: The Department found the facility failed to comply with Regulation 61-13, *Standards for Licensing Intermediate Care Facilities for Individuals with Intellectual Disabilities*, by failing to comply with multiple regulatory requirements, including, but not limited, to: failing to supervise residents, missing staff training documentation, inadequate infection control procedures, failing to ensure food and water safety, failing to accurately record the administration of medication, and resident safety issues.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of five thousand and seven hundred dollars ($5,700) against the facility. The facility was required to pay the full amount of the penalty split into two consecutive payments, with the first payment of two thousand and eight hundred fifty dollars ($2,850) due within thirty (30) days of executing the Consent Order and the second payment of two thousand and eight hundred fifty dollars ($2,850) due within sixty (60) days of executing the Consent Order. As a term of the Consent Order, the facility agreed to schedule and attend a compliance assistance meeting with the Department within forty-five (45) days of executing the Consent Order.

Remedial Action: The facility has made the required first payment and are scheduled to attend a compliance assistance meeting with DHEC staff on March 5, 2021.

Prior Enforcement Actions: None in the past five years.

Bureau of Radiological Health

Facility Type	Total # of Licensed Facilities
Radioactive Materials Medical Facility	163

4. Prisma Health Baptist Hospital – Columbia, SC

Inspections and Investigations: After the licensee notified the Department of a medical event in February 2020, the Department conducted an investigation and found that the licensee had both regulatory and South Carolina Radioactive Material License condition violations.

Violations: The Department found that the licensee failed to comply with Regulation 61-63, *Radioactive Materials (Title A)*, by failing to implement its "Prostate Seed Implant Radiation Safety Procedure," approved by the Department pursuant to South Carolina Radioactive Material License No. 076, Condition 18. The licensee's approved procedure requires that a urologist scope the bladder and urethral wall. The licensee failed to implement its approved procedure. The licensee also failed to comply with South Carolina Radioactive Material License No. 076, Amendment 129, Condition 18 by failing to have a urologist scope the bladder and urethral wall of a patient after a prostate seed radiation safety procedure was performed.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of seven thousand and five hundred dollars ($7,500) against the licensee. The licensee was required to pay the full amount of the penalty within thirty (30) days of executing the Consent Order.

Remedial Action: The licensee has made the required payment.

Prior Actions: None in the past five years.

Facility Type	Total # of Registered Facilities
Dental X-Ray Facility	1,788

5. Sandy Springs Dental Clinic – Pendleton, SC

Inspections and Investigations: The Department conducted a routine inspection in December 2019 and found that the registrant had repeatedly violated statutory and regulatory requirements.

Violations: The Department determined that the registrant violated the Atomic Energy and Radiation Control Act and Regulation 61-64, *X-Rays (Title B)*, for repeatedly failing to conduct equipment performance testing on dental x-ray systems when testing was due.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of one thousand and seven hundred dollars ($1,700) against the registrant. The registrant was required to pay two hundred and fifty-five dollars ($255) of the assessed penalty within 30 days of executing the Consent Order. The remaining one thousand and four hundred and forty-five dollars ($1,445) of the penalty will be stayed. The Department may conduct unannounced follow-up inspections after execution of this Consent Order.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five years.

6. John W. Cordray, Jr., DMD – Charleston, SC

Inspections and Investigations: The Department conducted a routine inspection in February 2020 and found that the registrant had repeatedly violated statutory and regulatory requirements.

Violations: The Department determined that the registrant violated the Atomic Energy and Radiation Control Act and Regulation 61-64, *X-Rays (Title B)*, for repeatedly failing to conduct equipment performance testing on dental x-ray systems when testing was due.

Enforcement Action: The parties agreed to resolve the matter with a consent order. The parties executed a consent order imposing a civil monetary penalty of one thousand and seven hundred dollars ($1,700) against the registrant. The registrant was required to pay two hundred and fifty-five dollars ($255) of the assessed penalty within 30 days of executing the Consent Order. The remaining one thousand and four hundred and forty-five dollars ($1,445) of the penalty will be stayed. The Department may conduct unannounced follow-up inspections after execution of this Consent Order.

Remedial Action: The registrant has made the required payment.

Prior Enforcement Actions: None in the past five years.

SUMMARY SHEET
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
March 11, 2021

_____ 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 January 1, 2021, through January 31, 2021.

3. **FACTS:** For the reporting period of January 1, 2021, through January 31, 2021, the Office of Environmental Affairs issued twenty-four (24) Consent Orders with total assessed civil penalties in the amount of eighty thousand, two hundred ninety-seven dollars ($80,297.00). Also, thirteen (13) Administrative Orders with total assessed civil penalties in the amount of forty-three thousand, four hundred dollars ($43,400.00) were reported during this period.

Bureau and Program Area	Administrative Orders	Assessed Penalties	Consent Orders	Assessed Penalties
Land and Waste Management				
UST Program	2	$41,900.00	6	$11,257.00
Aboveground Tanks	0	0	0	0
Solid Waste	0	0	0	0
Hazardous Waste	0	0	3	$18,860.00
Infectious Waste	0	0	0	0
Mining	0	0	0	0
SUBTOTAL	**2**	**$41,900.00**	**9**	**$30,117.00**
Water				
Recreational Water	1	$1,000.00	4	0
Drinking Water	0	0	3	0
Water Pollution	0	0	6	$33,880.00
Dam Safety	0	0	0	0
SUBTOTAL	**1**	**$1,000.00**	**13**	**$33,880.00**
Air Quality				
SUBTOTAL	**0**	**0**	**1**	**$15,000.00**
Environmental Health Services				
Food Safety	0	0	1	$1,300.00
Onsite Wastewater	10	$500.00	0	0
SUBTOTAL	**10**	**$500.00**	**1**	**$1,300.00**
OCRM				
SUBTOTAL	**0**	**0**	**0**	**0**
TOTAL	**13**	**$43,400.00**	**24**	**$80,297.00**

Submitted by:

Myra C. Reece
Director of Environmental Affairs

ENVIRONMENTAL AFFAIRS ENFORCEMENT REPORT
BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
March 11, 2021

BUREAU OF LAND AND WASTE MANAGEMENT

Underground Storage Tank Enforcement

1) Order Type and Number: Administrative Order 19-0407-UST
Order Date: January 21, 2021
Individual/Entity: **Robert Oggenfuss**
Facility: Today's Smokin Retailer
Location: 114 North Street
Clinton, SC
Mailing Address: Same
County: Laurens
Previous Orders: None
Permit/ID Number: 12942
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 S.C. Code Ann. § 44-2-60(A) (2018), and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs. 61-92.280.40(a); 280.70(a); 280.93(a); and, 280.110(c) (2012 and Supp. 2019).

Summary: Robert Oggenfuss (Individual/Entity) owns underground storage tanks (USTs) located in Laurens County, South Carolina. The Department issued Notices of Alleged Violations on May 21, 2019, and January 21, 2020. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation as follows: failed to submit evidence that the tanks contain less than one (1) inch of residue; failed to conduct tank tightness, line tightness, and line leak detector tests and begin conducting release detection for the tanks, or permanently close the tanks; failed to complete a Certificate of Financial Responsibility form and submit evidence of financial assurance; and, failed to pay annual tank registration fees for fiscal years 2013-2021.

Action: The Individual/Entity is required to: submit evidence the tanks contain less than one (1) inch of residue or conduct tank tightness, line tightness, and line leak detector tests, and begin release detection, or; submit a completed Tank Sludge Disposal form for permanent tank closure and a closure report after permanent closure of the tanks; submit a completed Certificate of Financial Responsibility form and evidence of financial assurance; and pay annual tank registration fees and associated late fees for fiscal years 2013-2021 in the amount of sixteen thousand, five hundred fifty-two dollars ($16,552.00), by March 15, 2021.The Department has assessed a civil penalty in the amount of thirteen thousand, one hundred fifty dollars ($13,150.00).The Individual/Entity shall pay a civil penalty in the amount of thirteen thousand, one hundred fifty dollars **($13,150.00)** by March 15, 2021.

Updates: The Individual/Entity did not file for a RFR.

2) Order Type and Number: Administrative Order 20-0061-UST
Order Date: January 26, 2021
Individual/Entity: **S and S Foods, LLC**
Facility: Power Trac 7
Location: 448 Ann Street
Pickens, SC 29671
Mailing Address: 1526 Brown Road
Anderson, SC 29621
County: Pickens
Previous Orders: None
Permit/ID Number: 11104
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, 280.31(a), 280.31(c), 280.70(a), 280.70(c), 280.93(a), 280.10(c) (2012 & Supp 2019).

Summary: S and S Foods, LLC (Individual/Entity) owns and operates underground storage tanks in Pickens County, South Carolina. The Department issued a Notice of Alleged Violation on February 12, 2020. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to pay to the Department annual underground storage tank registration fees; failed to operate and maintain corrosion protection equipment continuously; failed to inspect an impressed current system every sixty (60) days; failed to continue operation and maintenance of corrosion protection on a temporarily closed UST system; failed to properly abandon a temporarily closed system after twelve (12) months; failed to demonstrate financial responsibility for an UST system; and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity is required to: submit either passing metal integrity, tank tightness, and corrosion protection system test results for all USTs or a completed Tank and Sludge Disposal Form and within sixty (60) days of the Department's approval of the Tank and Sludge Disposal Form, permanently close the USTs and submit an UST Closure and Assessment Report; submit a completed Certificate of Financial Responsibility Form and submit evidence of financial assurance; and pay outstanding annual tank registration fees and associated late fees for fiscal years 2018, 2019, and 2020 in the amount of nine thousand, seventy-five dollars ($9,075.00) by March 12, 2021. The Department has assessed a civil penalty in the amount of twenty-eight thousand, seven hudred fifty dollars ($28,750.00). The Individual/Entity shall pay a civil penalty in the amount of twenty-eight thousand, seven hundred fifty dollars **($28,750.00)** by March 12, 2021.

Updates: The Individual/Entity did not file for a RFR.

3) Order Type and Number: Consent Order 19-0097-UST
Order Date: January 26, 2021
Individual/Entity: **HMS Ventures, LLC**

Facility: Richburg IGA Gas
Location: 3191 Lancaster Highway
Richburg, SC 29729
Mailing Address: 3104 Commerce Drive
Richburg, SC 29729
County: Chester
Previous Orders: None
Permit/ID Number: 18870
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, 280.30(a), 280.34(c), 280.40(a), 280.40(b)(1)(i)(B), 280.44(a), and 280.52 (2012 and Supp. 2019).

Summary: HMS Ventures, LLC (Individual/Entity) is the owner of underground storage tanks (USTs) located in Chester County, South Carolina. The Department conducted an inspection on March 1, 2019. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to ensure that releases due to spilling or overfilling do not occur; failed to provide records to the Department upon request; failed to provide an adequate release detection method; failed to conduct annual tightness test or have monthly monitoring of pressurized piping; failed to conduct annual test of automatic line leak detectors and/or sump sensors; and failed to investigate and confirm a suspected release within a reasonable time.

Action: The Individual/Entity is required to: submit line tightness test results for all underground storage tanks (USTs) at the facility; conduct a site check from the area underneath the 12,000-gallon regular UST spill bucket and submit the results to the Department by March 13, 2021. The Department has assessed a total civil penalty in the amount of three thousand, one hundred seven dollars ($3,107.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, one hundred seven dollars **($3,107.00)** by March 13, 2021.

Updates: None.

4) Order Type and Number: Consent Order 20-0051-UST
Order Date: January 26, 2021
Individual/Entity: **Ternion, LLC**
Facility: Reynolds Avenue Property
Location: 1801 Reynolds Avenue
Charleston, SC 29405
Mailing Address: 4930 Rivers Avenue
North Charleston, SC 29406
County: Charleston
Previous Orders: None
Permit/ID Number: 19895
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-60(A) et seq. (2018); and South Carolina Underground Storage Tank Control

Regulation, 7 S.C. Code Ann., Regs 61-92, 280.65, 280.93(a), 280.110(a)(1), 280.110(c), 280.111(a), and 280.113 (2012 & Supp 2019).

Summary: Ternion, LLC (Individual/Entity) owns and operates underground storage tanks in Charleston County, South Carolina. The Department issued a Notice of Alleged Violation on January 21, 2020. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to determine the full extent of a release in accordance with a schedule established by the Department; failed to demonstrate financial responsibility for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operations of petroleum USTs; failed to submit evidence of financial assurance to the Department within thirty (30) days after the owner or operator identifies a release from an UST required to be reported; failed to submit evidence of financial assurance to the Department upon request; failed to maintain evidence of all financial assurance mechanism used to demonstrate financial responsibility; and failed to maintain financial assurance until the tank has been permanently closed or undergoes a change-in-service or, if corrective action is required, after corrective action has been completed, and the tank has been permanently closed undergoes a change-in-service.

Action: The Individual/Entity is required to: submit both a completed Certificate of Financial Responsibility form and evidence of financial assurance; submit a Site Specific Work Plan for a Tier I Assessment Report; and within sixty (60) days of the approval of the SSWP, submit the assessment report. The Department has assessed a total civil penalty in the amount of twelve thousand, four hundred fifty dollars ($12,450.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand, four hundred fifty dollars **($2,450.00)** and pay a suspended penalty in the amount of ten thousand dollars ($10,000.00) should any requirement of the Order not be met by March 12, 2021.

Updates: None.

5)

Order Type and Number:	Consent Order 20-0178-UST
Order Date:	January 26, 2021
Individual/Entity:	**Kirtikaben Patel**
Facility:	Diya 2006 Inc.
Location:	100 East O'Neal Street Gaffney, SC 29340
Mailing Address:	Same
County:	Cherokee
Previous Orders:	None
Permit/ID Number:	01983
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(c)(1)(ii) (2012 & Supp. 2019).

Summary: Kirtikaben Patel (Individual/Entity) owns underground storage tanks (USTs) located in Cherokee County, South Carolina. The Department conducted an inspection on August 25, 2020. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Control Regulation, as follows: failed to

maintain an overfill prevention device on the 10,000-gallon premium gasoline tank.

Action: The Individual/Entity corrected the violation prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Updates: A passing overfill prevention equipment test was submitted to the Department on December 2, 2020. The civil penalty was paid in full on January 4, 2021.

6) Order Type and Number: Consent Order 20-0187-UST
Order Date: January 26, 2021
Individual/Entity: **Quick Pantry of Orangeburg, LLC**
Facility: Quick Pantry 16
Location: 232 Calhoun Avenue
Greenwood, SC 29649
Mailing Address: 2182 Magnolia Street
Orangeburg, SC 29115
County: Greenwood
Previous Orders: None
Permit/ID Number: 10483
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, 280.40(a)(2), and 280.43(d) (2012 and Supp. 2019).

Summary: Quick Pantry of Orangeburg, LLC (Individual/Entity) is the owner of underground storage tanks (USTs) located in Greenwood County, South Carolina. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to properly install, calibrate, operate, and maintain release detection equipment and failed to conduct automatic tank gauging properly.

Action: The Individual/Entity is required to: submit proof that the line leak detector for the plus underground storage tank has been repaired and/or replaced; conduct a line leak detector operability test, and submit the results to the Department by March 13, 2021. The Department has assessed a total civil penalty in the amount of three thousand, eight hundred dollars ($3,800.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, eight hundred dollars **($3,800.00)** by March 13, 2021.

Updates: None.

7) Order Type and Number: Consent Order 20-0196-UST
Order Date: January 26, 2021
Individual/Entity: **ECapital SC Land I, LLC**
Facility: Golf Club of SC at Crickentree
Location: 1084 Langford Road

Blythewood, SC 29016

Mailing Address: 225 Seven Farms Drive Suite 207
Charleston, SC 29492

County: Richland
Previous Orders: None
Permit/ID Number: 15050
Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-60(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.31(a), 280.70(a), 280.70(c), 280.93(a), and 280.110(c) (2012 & Supp 2019).

Summary: ECapital SC Land I, LLC (Individual/Entity) owns and operates underground storage tanks in Richland County, South Carolina. The Department conducted an inspection on August 9, 2019 and issued a Notice of Alleged Violation on May 8, 2020, to the new owner of record. The Individual/Entity has violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to pay to the Department annual underground storage tank registration fees; failed to operate and maintain corrosion protection equipment continuously; failed to continue operation and maintenance of corrosion protection on a temporarily closed UST system; failed to properly abandon a temporarily closed UST after twelve (12) months; failed to demonstrate financial responsibility for an UST system; and failed to submit evidence of financial assurance to the Department upon request.

Action: The Individual/Entity is required to: submit both a completed Certificate of Financial Responsibility form and evidence of financial assurance; pay outstanding annual tank registration fees and associated late fees for fiscal years 2019, 2020, and 2021 in the amount of two thousand, six hundred sixty-two dollars ($2,662.00); submit a completed Tank and Sludge Disposal Form and within sixty (60) days of the Department's approval of the Tank and Sludge Disposal Form, permanently close the USTs; and submit a UST Closure and Assessment Report to the Department by March 12, 2021. The Department has assessed a total civil penalty in the amount of six thousand, six hundred fifty dollars ($6,650.00). The Individual/Entity shall pay a **suspended penalty** in the amount of six thousand, six hundred fifty dollars **($6,650.00)** should any requirement of the Order not be met by March 12, 2021.

Updates: None.

8) Order Type and Number: Consent Order 20-0252-UST
Order Date: January 26, 2021
Individual/Entity: **Richland-Lexington Airport District**
Facility: Rental Car Maintenance Facility 2
Location: 880 Ermine Road
West Columbia, SC 29170

Mailing Address: 3260 Airport Boulevard Suite 1
West Columbia, SC 29170

County: Lexington
Previous Orders: None
Permit/ID Number: 18951

Violations Cited: The State Underground Petroleum Environmental Response Bank Act of 1988 (SUPERB Act), S.C. code Ann. § 44-2-60(A) et seq. (2018); and South Carolina Underground Storage Tank Control Regulation, 7 S.C. Code Ann., Regs 61-92, 280.31(a), 280.35(a)(1), 280.35(a)(2), 280.40(a), 280.40(a)(2), 280.40(a)(3), 280.44(a), and 280.45(b)(1) (2012 & Supp 2019).

Summary: Richland-Lexington Airport District (Individual/Entity) owns and operates underground storage tanks in Lexington County, South Carolina. The Department conducted an inspection and issued a Notice of Alleged Violation on September 18, 2020. The Individual/Entity violated the SUPERB Act and the South Carolina Underground Storage Tank Regulation, as follows: failed to maintain and operate a corrosion protection system; failed to complete spill bucket containment test every three (3) years; failed to inspect overfill prevention at least once every three (3) years; failed to provide an adequate release detection method; failed to properly maintain release detection; failed to complete the required release detection operability testing; failed to conduct an annual test of automatic line leak detectors; and failed to maintain records for at least one (1) year.

Action: The Individual/Entity is required to: conduct a hydrostatic test on the spill bucket for the UST and submit the results to the Department; if the hydrostatic test fails, conduct a site check, repair or replace the spill bucket, and conduct a follow-up hydrostatic test; submit release detection operability test results for the UST; submit overfill operability test results for the UST; submit line leak detector function check test results. The Department has assessed a total civil penalty in the amount of two thousand, four hundred thirty dollars ($2,430.00). The Individual/Entity shall pay a civil penalty in the amount of nine hundred dollars **($900.00)** and pay a suspended penalty in the amount of one thousand, five hundred thirty dollars ($1,530.00) should any requirement of the Order not be met by March 12, 2021.

Updates: The release detection operability test results, line leak detector function check results, overfill operability test results, and hydrostatic test results have been received. The civil penalty was paid February 16, 2021.

Hazardous Waste Enforcement

9)

Order Type and Number:	Consent Order 20-15-HW
Order Date:	January 6, 2021
Individual/Entity:	**Riggins Garment Care**
Facility:	Riggins Garment Care
Location:	1903 North Main Street Anderson, SC 29625
Mailing Address:	Same
County:	Anderson
Previous Orders:	None
Permit/ID Number:	SCD 981 760 226
Violations Cited:	The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2019), and the South

Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2019).

Summary: Riggins Garment Care (Individual/Entity) is a full-service dry cleaning and laundering facility located Anderson County, South Carolina. The Department conducted an inspection on September 21, 2020. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations, as follows: failed to receive an extension from the Department granting hazardous waste to remain onsite for longer than one hundred eighty (180) days; failed to mark or label its containers with the words "Hazardous Waste," an accumulation start date, and an indication of the hazards of the contents; failed to attempt to make arrangements with local emergency responders; failed to ensure employees who handle hazardous waste were familiar with proper waste handling and emergency procedures; and failed to retain onsite copies of all notices and certifications for hazardous waste subject to offsite treatment, storage, or disposal.

Action: The Individual/Entity is required to: submit hazardous waste training documentation for employees who handle hazardous waste by February 8, 2021. The Department assessed a total civil penalty in the amount of three thousand, three hundred sixty dollars ($3,360.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand three hundred sixty dollars **($3,360.00)**.

Updates: The civil penalty was paid in full on December 16, 2020.

10)

Order Type and Number:	Consent Order 20-16-HW
Order Date:	January 6, 2021
Individual/Entity:	**Bommer Industries, Inc. – Gaffney**
Facility:	Bommer Industries, Inc. – Gaffney
Location:	584 Peachoid Road Gaffney, SC 29341
Mailing Address:	P.O. Box 187 Landrum, SC 29356
County:	Cherokee
Previous Orders:	None
Permit/ID Number:	SCD 980 843 486
Violations Cited:	The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2019), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2019).

Summary: Bommer Industries, Inc. (Individual/Entity) is a manufacturer of custom-built hinges with a finishing and electroplating operation located in Cherokee County, South Carolina. The Department conducted an inspection on July 30, 2020. The Individual/Entity violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations, as follows: failed to determine if a solid waste was a hazardous waste; failed to file a revised or new Notification Form with the Department whenever a new hazardous waste was produced and the company contact changed; failed to mark or label its containers with the words "Hazardous Waste" and an indication of the hazards of the contents; failed to have a hazardous waste training plan for

the facility that was director by a person trained in hazardous waste; failed to receive an extension from the Department granting hazardous waste to remain onsite for longer than ninety (90) days; failed to clean up a hazardous waste spill that occurred during processing; failed to submit Quarterly Reports in accordance with the required instructions; failed to have a contingency plan that included the content as described in the Regulations; failed to include the locations of the water supply and the identification of the on-site notification systems in the quick reference guide; and failed to maintain universal waste lamps in a manner to prevent a release and to keep such containers closed.

Action: The Individual/Entity corrected all violations prior to the issuance of the Order. The Department assessed a total civil penalty in the amount of twelve thousand dollars ($12,000.00). The Individual/Entity shall pay a civil penalty in the amount of twelve thousand dollars **($12,000.00)**.

Updates: The civil penalty was paid in full on January 4, 2021.

11)

Order Type and Number:	Consent Order 20-17-HW
Order Date:	January 12, 2021
Individual/Entity:	**Motor City Racks**
Facility:	Motor City Racks
Location:	597 Ford Road Gaffney, SC 29340
Mailing Address:	Same
County:	Cherokee
Previous Orders:	None
Permit/ID Number:	SCR 000 785 618
Violations Cited:	The South Carolina Hazardous Waste Management Act**,** S.C. Code Ann. §§ 44-56-10 et seq. (2018), and the South Carolina Hazardous Waste Management Regulation, 6 and 7 S.C. Code Ann. Regs. 61-79 (2012 and Supp. 2018).

Summary: Motor City Racks (Individual/Entity) is a manufacturer of custom racking systems located Cherokee County, South Carolina. The Department conducted an inspection on June 25, 2020. The Individual/Entity has violated the South Carolina Hazardous Waste Management Act and the Hazardous Waste Management Regulations, as follows: failed to meet the conditions for exemption ; failed to accurately determine if the waste was hazardous; failed to maintain records supporting its hazardous waste determinations, including records that identify whether a solid waste is a hazardous waste;failed to maintain records for at least three (3) years from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal; failed to file a revised or new Notification form whenever the information previously provided became outdated or inaccurate; failed to clean up any hazardous waste discharge that occurred during generation or processing or storage and take such other action as may be required or approved by Federal, State, or local officials so that the hazardous waste discharge no longer presents a hazard to human health or the environment; and failed to maintain and operate the facility to minimize the possibility of a fire, explosion, or any unplanned sudden or nonsudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

Action: The Individual/Entity corrected all violations prior to the issuance of the Order. The Department assessed a total civil penalty in the amount of three thousand, five hundred dollars ($3,500.00). The Individual/Entity shall pay a civil penalty in the amount of three thousand, five hundred dollars **($3,500.00)**.

Updates: The Individual/Entity has paid the assessed civil penalty.

BUREAU OF WATER

Recreational Waters Enforcement

12)

Order Type and Number:	Administrative Order 20-140-RW
Order Date:	December 17, 2020
Individual/Entity:	**MP Owner 1, LLC**
Facility:	Sage at 1240
Location:	1240 Winnowing Way Mount Pleasant, SC 29466
Mailing Address:	92 River Road Summit, NJ 07901
County:	Charleston
Previous Orders:	None
Permit/ID Number:	10-1200B
Violations Cited:	S.C. Code Ann. Regs. 61-51(J)

Summary: MP Owner 1, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Charleston County, South Carolina. The Department conducted inspections on July 21, 2020, and August 10, 2020, and violations were issued for failure to properly operate and maintain. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: the cyanuric acid level was above the water quality standards acceptable limit; only one "Shallow Water – No Diving Allowed" sign was posted; only one "No Lifeguard On Duty - Swim At Your Own Risk" sign was posted; there was debris in the skimmer baskets; and the chlorine level was not within the acceptable range of water quality standards.

Action: The Individual/Entity has corrected all violations. The Department has assessed a total civil penalty in the amount of one thousand dollars ($1,000.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand dollars **($1,000.00)**.

Updates: The Individual/Entity has paid the civil penalty. This Order has been closed.

13)

Order Type and Number:	Consent Order 21-001-RW
Order Date:	January 11, 2021
Individual/Entity:	**Quality Investment, Inc.**
Facility:	Ramada Limited

Location:	70 Contractors Way Ridgeway, SC 29130
Mailing Address:	Same
County:	Fairfield
Previous Orders:	None
Permit/ID Number:	20-014-1
Violations Cited:	S.C. Code Ann. Regs. 61-51.J.22

Summary: Quality Investment, Inc. (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Fairfield County, South Carolina. The Department issued a Notice of Enforcement Conference on November 30, 2020, as a result of a review of inspection records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to fill in or remove the pool, which has been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: correct all deficiencies and any upgrades required to bring the pool into compliance with Regulation 61-51 and contact the Department to schedule an inspection to verify the completed work by April 11, 2021. The Individual/Entity will be required to properly fill in or remove the pool by May 11, 2021, if the requirement to bring the pool into compliance with the Regulation is not met by the specified date. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four hundred dollars **($400.00)** should any requirement of the Order not be met.

Updates: On January 7, 2021, the Department conducted a technical assistance inspection of the pool with the Individual/Entity to provide an inspection checklist of the deficiencies and required upgrades.

14)

Order Type and Number:	Consent Order 21-002-RW
Order Date:	January 11, 2021
Individual/Entity:	**S.N. Company, LLC**
Facility:	Palmetto Inn
Location:	3311 Meadors Road Florence, SC 29501
Mailing Address:	Same
County:	Florence
Previous Orders:	None
Permit/ID Number:	21-036-1 & 21-036-2
Violations Cited:	S.C. Code Ann. Regs. 61-51.J.22

Summary: S.N. Company, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool and a kiddie pool located in Florence County, South Carolina. The Department issued a Notice of Enforcement Conference on November 20, 2020, as a result of a review of inspection records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to fill in or remove the pool and kiddie pool, which have been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: submit to the Department for review and approval, a plan detailing the procedure and materials to be used to properly fill in or remove the pool and kiddie pool by January 26, 2021; and, within sixty days of the Department's approval of the plan, complete the procedure in accordance with the plan and contact the Department to schedule an inspection to verify the completed work. The Department has assessed a total civil penalty in the amount of eight hundred dollars ($800.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of eight hundred dollars **($800.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has submitted a plan to properly fill in the pool and kiddie pool and the plan has been approved.

15)

Order Type and Number:	Consent Order 21-003-RW
Order Date:	January 11, 2021
Individual/Entity:	**Ronald Barry Grice, Individually and d.b.a. Marlboro Country Club**
Facility:	Marlboro Country Club
Location:	404 Country Club Drive Bennettsville, SC 29512
Mailing Address:	205 Oakwood Drive Mount Holly, NC 28120
County:	Marlboro
Previous Orders:	None
Permit/ID Number:	34-001-2
Violations Cited:	S.C. Code Ann. Regs. 61-51.J.22

Summary: Ronald Barry Grice, Individually and d.b.a. Marlboro Country Club (Individual/Entity) owns and is responsible for the proper operation and maintenance of a kiddie pool located in Marlboro County, South Carolina. The Department issued a Notice of Enforcement Conference on December 4, 2020, as a result of a review of inspection records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to fill in or remove the kiddie pool, which has been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: submit to the Department for review and approval, a plan detailing the procedure and materials to be used to properly fill in or remove the kiddie pool by January 26, 2021; and, within sixty days of the Department's approval of the plan, complete the procedure in accordance with the plan and contact the Department to schedule an inspection to verify the completed work. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four hundred dollars **($400.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has submitted a plan to properly fill the kiddie pool and the plan has been approved.

16)

Order Type and Number:	Consent Order 21-004-RW
Order Date:	January 19, 2021

Individual/Entity:	**Austin Woods 2017, LLC**
Facility:	Austin Woods Apartments
Location:	7648 Sumter Highway Columbia, SC 29209
Mailing Address:	Same
County:	Richland
Previous Orders:	None
Permit/ID Number:	40-083-1
Violations Cited:	S.C. Code Ann. Regs. 61-51.J.22

Summary: Austin Woods 2017, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a pool located in Richland County, South Carolina. The Department issued a Notice of Enforcement Conference on November 23, 2020, as a result of a review of inspection records. The Individual/Entity has violated the Public Swimming Pools Regulation as follows: failed to fill in or remove the pool, which has been permanently closed for a period in excess of twenty-four consecutive months.

Action: The Individual/Entity is required to: correct all deficiencies and any upgrades required to bring the pool into compliance with Regulation 61-51 and contact the Department to schedule an inspection to verify the completed work by July 19, 2021. The Individual/Entity will be required to properly fill in or remove the pool by August 19, 2021, if the requirement to bring the pool into compliance with the Regulation is not met by the specified date. The Department has assessed a total civil penalty in the amount of four hundred dollars ($400.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four hundred dollars **($400.00)** should any requirement of the Order not be met.

Updates: On December 9, 2020, the Department conducted a technical assistance inspection of the pool with the Individual/Entity to provide an inspection checklist of the deficiencies and required upgrades.

Drinking Water Enforcement

17)

Order Type and Number:	Consent Order 21-001-DW
Order Date:	January 19, 2021
Individual/Entity:	**Whitesides General Store, LLC**
Facility:	Whitesides General Store
Location:	1041 East Main Street Smyrna, SC 29743
Mailing Address:	1011 Main Street Smyrna, SC 29743
County:	York
Previous Orders:	None
Permit/ID Number:	4679029
Violations Cited:	S.C. Code Ann. Regs. 61-58.17.K(1)

Summary: Whitesides General Store, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS)

located in York County, South Carolina. On December 7, 2020, 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 tested present for total coliform and E. coli, which resulted in a violation of the maximum contaminant level for E. coli.

Action: The Individual/Entity is required to: submit an investigative report and a corrective action plan to address the causes of the total coliform present results at the PWS by February 19, 2021. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars (**$4,000.00**) should any requirement of the Order not be met.

Updates: The Individual/Entity submitted an investigative report and a corrective action plan. The corrective action plan has been completed.

18)

Order Type and Number:	Consent Order 21-002-DW
Order Date:	January 26, 2021
Individual/Entity:	**KC Holdings Group, LLC**
Facility:	A&L Mobile Home Park #9 & A&L Mobile Home Park #10
Location:	805 Quail Road Johnsonville, SC 29555
Mailing Address:	25 Chapel Creek Road Pawley's Island, SC 29585
County:	Florence
Previous Orders:	None
Permit/ID Number:	2160126 & 2160133
Violations Cited:	S.C. Code Ann. Regs. 61-58.7 & 61-58.8.B

Summary: KC Holdings Group, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of two public water systems (PWSs) located in Florence County, South Carolina. The Department conducted an inspection of PWS No. 2160126 on October 5, 2020, and it was rated unsatisfactory for failure to properly operate and maintain, and failure to provide an up-to-date emergency preparedness plan. The Individual/Entity has violated the State Primary Drinking Water Regulation as follows: a complete procedures manual with written programs and logs was not provided for Department review; an up-to-date emergency preparedness plan was not provided for Department review; the well serving PWS No. 2160133 was offline, and the PWSs were connected; the well houses were dirty; and, the well house doors did not have locks.

Action: The Individual/Entity is required to: correct the deficiencies and submit to the Department for review and approval a complete procedures manual and emergency preparedness plan by February 26, 2021. The Department has assessed a total civil penalty in the amount of twelve thousand dollars ($12,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of twelve thousand dollars ($**12,000.00**) should any requirement of the Order not be met.

Updates: None.

19) Order Type and Number: Consent Order 21-003-DW
Order Date: January 26, 2021
Individual/Entity: **Wildwater, LTD**
Facility: Wildwater Chattooga
Location: 1251 Academy Road S-37-14
Long Creek, SC 29658
Mailing Address: P.O. Box 309
Long Creek, SC 29658
County: Oconee
Previous Orders: None
Permit/ID Number: 3774004
Violations Cited: S.C. Code Ann. Regs. 61-58.17.K(1)

Summary: Wildwater, LTD (Individual/Entity) owns and is responsible for the proper operation and maintenance of a public water system (PWS) located in Oconee County, South Carolina. On November 9, 2020, 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 tested present for total coliform and E. coli, which resulted in a violation of the maximum contaminant level for E. coli.

Action: The Individual/Entity is required to: submit an investigative report and a corrective action plan to address the causes of the total coliform present results at the PWS by February 26, 2021. The Department has assessed a total civil penalty in the amount of four thousand dollars ($4,000.00). The Individual/Entity shall pay a **stipulated penalty** in the amount of four thousand dollars (**$4,000.00**) should any requirement of the Order not be met.

Updates: The Individual/Entity submitted an investigative report and a corrective action plan. The corrective action plan has been completed.

Water Pollution Enforcement

20) Order Type and Number: Consent Order 20-052-W
Order Date: January 6, 2021
Individual/Entity: **City of Walhalla Sewer Collection System**
Facility: City of Walhalla Sewer Collection System
Location: 206 North Church Street
Walhalla, SC 29691
Mailing Address: Same
County: Oconee
Previous Orders: None
Permit/ID Number: SSS000064

Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) and Water Pollution Control Permits Regulation S.C. Code Ann. Regs. 61-9.610.3(a) and 61-9.610(c)

Summary: City of Walhalla Sewer Collection System (Individual/Entity) owns and is responsible for a satellite sewer collection system located in Oconee County, South Carolina. On July 20, 2020, the Department issued a Notice of Alleged Violation as result of an unsatisfactory inspection of the collection system. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation, as follows: failed to properly manage, operate and maintain at all times all parts of its sewer systems and failed to take all reasonable steps to prevent, stop and mitigate the impact of releases of wastewater to the environment.

Action: The Individual/Entity is required to submit a Compliance Attainment Plan (Plan) by March 8, 2021, outlining actions necessary to resolve deficiencies of its collection systemand must include: submit a Preliminary Engineering Report (PER) regarding improvements to the collection system by May 6, 2021; development and implementation of a written Operation and Maintenance plan by July 5, 2021; and, submit construction permit applications for certain pump station upgrades within one hundred twenty (120) days from Department approval of the PER. All construction activities must be completed within one hundred eighty (180) days from issuance of applicable Construction Permits issued by the Department. The Department has assessed a total civil penalty in the amount of one thousand, four hundred dollars ($1,400.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand, four hundred dollars **($1,400.00)** by February 5, 2021.

Updates: The Individual/Entity has paid the assessed civil penalty.

21) Order Type and Number: Consent Order 20-053-W
Order Date: January 6, 2021
Individual/Entity: **Town of Greeleyville**
Facility: Town of Greeleyville WWTF
Location: West of the Town of Greeleyville and south of Society Street Extension
Mailing Address: P.O. Box 212
Greeleyville, SC 29056
County: Williamsburg
Previous Orders: None
Permit/ID Number: ND0077968
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d), Water Pollution Control Permits, S.C. Code Ann. Regs.61-9.505.41(a)

Summary: Town of Greeleyville (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) in Williamsburg County, South Carolina. On February 24, 2020, a Notice of Violation was issued as a result of E. coli violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation as follows: failed to comply with the effluent limits for E.coli.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by February 6, 2021; demonstrate a six (6) monitoring event compliance confirmation period subsequent to completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of four thousand, nine hundred dollars ($4,900.00). The Individual/Entity shall pay a civil penalty in the amount of four thousand, nine hundred dollars **($4,900.00)** by February 28, 2021.

Updates: The Individual/Entity paid the assessed civil penalty.

22) Order Type and Number: Consent Order 20-054-W
Order Date: January 6, 2021
Individual/Entity: **Sun Chemical Corporation**
Facility: Bushy Park WWTF
Location: 1506 Bushy Creek Park Road
Goose Creek, SC 29445
Mailing Address: Same
County: Berkeley
Previous Orders: 17-059-W ($2,520.00)
Permit/ID Number: SC0003441
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) and Water Pollution Control Permits Regulation S.C. Code Ann. Regs. 61-9.122.41(a)

Summary: Sun Chemical Corporation (Individual/Entity) owns and is responsible for a wastewater treatment facility (WWTF) located in Berkeley County, South Carolina. On August 3, 2020, a Notice of Violation was issued as a result of biochemical oxygen demand (BOD) violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation as follows: failed to comply with the permitted effluent limitations for BOD.

Action: The Individual/Entity is required to: submit a written notification of the completion date for all corrective actions necessary to resolve the violations by February 6, 2021; demonstrate a six (6) event compliance confirmation period subsequent to completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of five thousand, six hundred dollars ($5,600.00). The Individual/Entity shall pay a civil penalty in the amount of five thousand, six hundred dollars **($5,600.00)** by February 5, 2021.

Updates: The Individual/Entity paid the assessed civil penalty and submitted notification of the completion date for all corrective actions.

23) Order Type and Number: Consent Order 21-001-W
Order Date: January 21, 2021

Individual/Entity: **Wellford Glen LLC**
Facility: Wellford Estates Trailer Park
Location: Fort Prince Boulevard
Spartanburg, SC
Mailing Address: P.O. Box 427
Arcadia, SC 29320
County: Spartanburg
Previous Orders: None
Permit/ID Number: SC0030571
Violations Cited: Pollution Control Act, S.C. Code Ann. § 48-1-110(d) (2008 & Supp. 2019), and Water Pollution Control Permits Regulation, S.C. Code Ann. Regs. 61-9.122.41(a) (2011), and NPDES Permit SC0030571

Summary: Wellford Glen, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a wastewater treatment facility (WWTF) in Spartanburg County, South Carolina. On March 9, 2020, a Notice of Violation was issued as a result of E. coli violations reported on discharge monitoring reports submitted to the Department. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permits Regulation as follows: failed to comply with the effluent limits for E.coli.

Action: The Individual/Entity is required to: submit written notification of the completion date for all corrective actions necessary to resolve the violations by February 6, 2021; demonstrate a six (6) event compliance confirmation period subsequent to completion of corrective actions; and, implement engineered upgrades to the WWTF should additional violations be observed during the compliance confirmation period. The Department has assessed a total civil penalty in the amount of two thousand three hundred eighty dollars ($2,380.00). The Individual/Entity shall pay a civil penalty in the amount of two thousand three hundred eighty dollars **($2,380.00)** by February 21, 2021.

Updates: The Individual/Entity has paid the assessed civil penalty.

24) Order Type and Number: Consent Order 21-002-W
Order Date: January 21, 2021
Individual/Entity: **Titan Peach Packaging Farm**
Facility: Titan Peach Packaging Farm
Location: 5 RW Dubose Road
Ridge Spring, SC 29129
Mailing Address: Same
County: Edgefield
Previous Orders: 19-027-W ($4,200.00)
Permit/ID Number: N/A
Violations Cited: Pollution Control Act, S.C Code Ann § 48-1-90 (A) (1) (2008 & Supp. 2019) and South Carolina Standards for Permitting of Agricultural Animal Facilities (2007).

Summary: Titan Peach Packaging Farm (Individual/Entity) owns and is responsible for a peach packaging facility in Edgefield County, South Carolina. On July 6, 2020, a Notice of Deficiency was issued as a result of deficiencies observed during an operation

and maintenance inspection at the facility. The Individual/Entity has violated the Pollution Control Act as follows: discharged wastewater into the environment, including waters of the state, in a manner other than in compliance with a permit issued by the Department. The Individual/Entity has also violated the South Carolina Standards for Agricultural Animal Facilities as follows: failed to maintain its lagoon to withstand a twenty-five (25) year twenty-four (24) hour rain event and applied wastewater onto a saturated spray field.

Action: The Individual/Entity is required to: complete construction of the spray field expansion by March 30, 2021; and, install water level measuring devices in its lagoons by February 15, 2021. The Department has assessed a total civil penalty in the amount of nine thousand, six hundred dollars ($9,600.00). The Individual/Entity shall pay a civil penalty in the amount of nine thousand six hundred dollars **($9,600.00)** by February 21, 2021.

Updates: The Individual/Entity notified the Department of the installation of water level measuring devices and has paid the assessed civil penalty.

25) Order Type and Number: Consent Order 21-003-W
Order Date: January 26, 2021
Individual/Entity: **Cane Lime & Supply, LLC**
Facility: Cane Lime & Supply, LLC Composting Facility
Location: 1416 North Williamsburg County Highway Williamsburg, SC
Mailing Address: P.O. Box 2472 Lexington, SC 29071
County: Williamsburg
Previous Orders: 20-006-W ($12,000.00)
Permit/ID Number: ND0087556
Violations Cited: Pollution Control Act, S.C Code Ann §§ 48-1- 110 (d) and 48-1-130 (2008 & Supp. 2019); Water Pollution Control Permits, S.C. Code Ann Regs. 61-9.505.41 (a) and (l) (4) (2011).

Summary: Cane Lime & Supply, LLC (Individual/Entity) owns and is responsible for the proper operation and maintenance of a composting facility (Facility) in Williamsburg County, South Carolina. On February 7, 2020, the Individual/Entity and the Department entered into Consent Order 20-006-W as a result of the Individual/Entity's failure to submit annual reports as required by its State Land Application Permit. The Individual/Entity has violated the Pollution Control Act and the Water Pollution Control Permit Regulation as follows: failed to submit full payment of the civil penalty assessed by Consent Order 20-006-W and failed to submit annual reports as required by its Permit.

Action: The Individual/Entity has submitted the required annual report. The Department has assessed a total civil penalty in the amount of ten thousand dollars ($10,000.00). The Individual/Entity shall pay a civil penalty in the amount of ten thousand dollars **($10,000.00)** by November 15, 2021.

Updates: The Individual/Entity submitted an installment payment toward the assessed civil penalty.

BUREAU OF AIR QUALITY

26) Order Type and Number: Consent Order 21-001-A
Order Date: January 26, 2021
Individual/Entity: **Jasper Pellets, LLC**
Facility: Jasper Pellets
Location: 523 Nimmer Turf Road
Ridgeland, SC 29936
Mailing Address: 4232 Tillman Bluff Road
Valdosta, GA 31602
County: Jasper
Previous Orders: None
Permit/ID Number: 1360-0050
Violations Cited: US EPA Regulations at 40 CFR 52.21(a)(2)(iii) and S.C. Code Ann. Regs. 61-62.5, Standard No. 7, Prevention of Significant Deterioration, Section (a)(2)(iii), and S.C. Code Ann. Regs. 61-62.1, Sections II.A.1.a, II.A.3, II.E.2.a, and II.E.2.b

Summary: Jasper Pellets, LLC (Individual/Entity) processes wood shavings and sawdust into wood pellets at its facility in Jasper County, South Carolina. The Individual/Entity has violated U.S. EPA Regulations and South Carolina Air Pollution Control Regulation, as follows: failed to obtain a construction permit from the Department prior to beginning construction of new equipment and failed to submit written notification to the Department of the date construction was commenced for the new equipment.

Action: The Individual/Entity is required to: henceforth obtain a construction permit from the Department prior to constructing, altering, or adding to a source of air contaminants and submit written notification to the Department of the date construction is commenced for new equipment. The Department has assessed a total civil penalty in the amount of fifteen thousand dollars ($15,000.00). The Individual/Entity shall pay a civil penalty in the amount of fifteen thousand dollars **($15,000.00)** by February 26, 2021.

Updates: The Department issued Synthetic Minor Construction Permit 1360-0050-CC to Jasper Pellets.

BUREAU OF ENVIRONMENTAL HEALTH SERVICES

Food Safety Enforcement

27) Order Type and Number: Consent Order 2020-20-02-023
Order Date: January 4, 2021
Individual/Entity: **Sciortino's Trattoria**

Facility:	Sciortino's Trattoria
Location:	3734 Pelham Road Greenville, SC 29615
Mailing Address:	Same
County:	Greenville
Previous Orders:	None
Permit Number:	23-206-09995
Violations Cited:	S.C. Code Ann. Regs. 61-25

Summary: Sciortino's Trattoria (Individual/Entity) is a restaurant located in Greenville County, South Carolina. The Department conducted inspections on June 18, 2019, February 26, 2020, March 4, 2020, and March 5, 2020. The Individual/Entity has violated the South Carolina Retail Food Establishment Regulation as follows: obscured, covered, defaced, relocated, or removed the grade decal that was posted by the Department and 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. The Individual/Entity corrected all violations prior to the issuance of the Order. The Department has assessed a total civil penalty in the amount of one thousand three hundred dollars ($1,300.00). The Individual/Entity shall pay a civil penalty in the amount of one thousand three hundred dollars **($1,300.00)**.

Updates: The Individual/Entity has entered into a payment plan with the Department.

On Site Wastewater Enforcement

28)

Order Type and Number:	Administrative Order 20-102-OSWW
Order Date:	January 6, 2021
Individual/Entity:	**LGB Construction/Adam Brown**
Facility:	LGB Construction/Adam Brown
Location:	Highway 76 W Grey Court, SC 29645
Mailing Address:	161 Argyle Lane Laurens, SC 29360
County:	Laurens
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: LGB Construction and Adam Brown (Individual/Entity) previously held a Department issued license to repair and construct OSWW systems. The Department conducted an investigation on January 10, 2020, when it was determined no Approval to Operate Contractor Self-Install form was submitted for Permit #2017100020 (installed September 20, 2019). On February 26, 2020, the Department determined that the Individual/Entity's license expired in October of 2018. The Individual/Entity has violated the South Carolina Onsite Wastewater (OSWW) Systems Regulation as follows: failed to

maintain a valid license to engage in the business of constructing and repairing onsite sewage treatment and disposal systems.

Action: The Individual/Entity is required to cease and desist installing or repairing the OSWW systems until a valid license is obtained from the Department. The Department has assessed a total civil penalty in the amount of five hundred dollars ($500.00). The Individual/Entity shall pay a civil penalty in the amount of five hundred dollars **($500.00)** by February 5, 2021.

Updates: On February 23, 2021, the Department mailed and e-mailed a payment demand letter to the Individual/Entity.

29)

Order Type and Number:	Administrative Order 20-122-OSWW
Order Date:	January 6, 2021
Individual/Entity:	**William Matthew Turner**
Facility:	William Matthew Turner
Location:	410 Chauga Road Westminster, SC 29693
Mailing Address:	Same
County:	Oconee
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: William Matthew Turner (Individual/Entity) owns property located in Oconee County, South Carolina. The Department conducted an investigation on November 5, 2020, 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has met the requirements of the Order. This Order has been closed.

30)

Order Type and Number:	Administrative Order 20-125-OSWW
Order Date:	January 6, 2021
Individual/Entity:	**Jan Goode and Donnie Ree Goode, II**
Facility:	Jan Goode and Donnie Ree Goode, II
Location:	5230 Clifton Glendale Road Clifton, SC 29307

Mailing Address:	P.O. Box 353 Drayton, SC 29333
County:	Spartanburg
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Jan Goode and Donnie Ree Goode, II (Individual/Entity) own property located in Spartanburg County, South Carolina. The Department conducted an investigation on December 1, 2020, 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has not complied with the Order and it has been referred to the Office of General Counsel for further enforcement.

31)

Order Type and Number:	Administrative Order 20-127-OSWW
Order Date:	January 11, 2021
Individual/Entity:	**Frank Kitchings**
Facility:	Frank Kitchings
Location:	104 Burnt Oak Lane Leesville, SC 29070
Mailing Address:	Same as Location
County:	Lexington
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Frank Kitchings (Individual/Entity) owns property located in Lexington County, South Carolina. The Department conducted an investigation on December 4, 2020, 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has met the requirements of the Order. This Order has been closed.

32) Order Type and Number: Administrative Order 20-128-OSWW
Order Date: January 21, 2021
Individual/Entity: **Rajesh Desor**
Facility: Rajesh Desor
Location: 463 Kay Drive
Easley, SC 29640
Mailing Address: Same
County: Pickens
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Rajesh Desor (Individual/Entity) owns property located in Pickens County, South Carolina. The Department conducted an investigation on November 18, 2020, and November 19, 2020, 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has met the requirements of the Order. This Order has been closed.

33) Order Type and Number: Administrative Order 20-130-OSWW
Order Date: January 21, 2021
Individual/Entity: **Heirs of Richard Gadson**
Facility: Heirs of Richard Gadson
Location: 1236 May River Road
Bluffton, SC 29910
Mailing Address: P.O. Box 3912
Bluffton, SC 28810
County: Beaufort

Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Heirs of Richard Gadson (Individual/Entity) owns property located in Beaufort County, South Carolina. The Department conducted an investigation on November 23, 2020 and observed evidence of recent 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Department is actively working with the public sewer provider and the Town of Bluffton to have the property connected to public sewer, as a corrective action.

34) Order Type and Number: Administrative Order 20-131-OSWW
Order Date: January 21, 2021
Individual/Entity: **Karen Ellison**
Facility: Karen Ellison
Location: 1803 Agnew Road
Starr, SC 29684
Mailing Address: P.O. Box 292
Williamston, SC 29697
County: Anderson
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Karen Ellison (Individual/Entity) owns property located in Anderson County, South Carolina. The Department conducted an investigation on November 17, 2020, 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall

pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has met the requirements of the Order. This Order has been closed.

35) Order Type and Number: Administrative Order 20-132-OSWW
Order Date: January 21, 2021
Individual/Entity: **Kenneth Broughton, Alfred Broughton, Sam Wright, and other Heirs of Sharlow Broughton**
Facility: Kenneth Broughton, Alfred Broughton, Sam Wright, and other Heirs of Sharlow Broughton
Location: 13892 Old Number Six Highway Eutawville, SC 20948
Mailing Address: P.O. Box 136 Vance, SC 29163
County: Orangeburg
Previous Orders: None
Permit Number: None
Violations Cited: S.C. Code Ann. Regs. 61-56

Summary: Kenneth Broughton, Alfred Broughton, Sam Wright, and other Heirs of Sharlow Broughton (Individual/Entity) owns property located in Orangeburg County, South Carolina. The Department conducted an investigation on November 19, 2020, 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Individual/Entity has met the requirements of the Order. This Order has been closed.

36) Order Type and Number: Administrative Order 21-001-OSWW
Order Date: January 21, 2021
Individual/Entity: **Timothy Way**
Facility: Timothy Way
Location: 303 E. Belvue Road

	Taylors, SC 29687
Mailing Address:	Same as Location
County:	Greenville
Previous Orders:	None
Permit Number:	None
Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Timothy Way (Individual/Entity) owns property located in Greenville County, South Carolina. The Department conducted an investigation on December 11, 2020, 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The Department has been contacted by the Individual/Entity who stated the sewer service line to the house had been installed, although a utility company had to make adjustments before the final connection and inspection could be made to the public sewer line.

37)	Order Type and Number:	Administrative Order 20-129-OSWW
	Order Date:	January 25, 2021
	Individual/Entity:	**Greenleaf Investment Partners L049A, LLC**
	Facility:	Greenleaf Investment Partners L049A, LLC
	Location:	8614 Anchor Street Spartanburg, SC 29303
	Mailing Address:	3081 Holcomb Bridge Road Norcross, GA 30071
	County:	Spartanburg
	Previous Orders:	None
	Permit Number:	None
	Violations Cited:	S.C. Code Ann. Regs. 61-56

Summary: Greenleaf Investment Partners L049A, LLC (Individual/Entity) owns property located in Spartanburg County, South Carolina. The Department conducted an investigation on December 10, 2020, 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, 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. The Department has assessed a total civil penalty in the amount of five thousand dollars ($5,000.00). The Individual/Entity shall pay a **suspended penalty** in the amount of five thousand dollars **($5,000.00)** should any requirement of the Order not be met.

Updates: The attorney for the Individual/Entity has contacted the Department and is in the process of evicting the tenants of the Site.

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

SUMMARY SHEET
SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

March 11, 2021

(X) ACTION/DECISION
( ) INFORMATION

I. **TITLE:** Request for Placement of Brorphine into Schedule I for Controlled Substances in South Carolina

II. **SUBJECT:** Placement of Brorphine in Schedule I for Controlled Substances

II. **FACTS:**

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

South Carolina Section 44-53-160(C) states:

> If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairmen of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee, and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

The Acting Administrator of the Drug Enforcement Administration ("DEA") issued a temporary order to schedule 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2Hbenzo[d]imidazol-2-one (commonly known as brorphine), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act. This action is based on a finding by the Acting Administrator that the placement of brorphine in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle brorphine. This temporary order will

be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2). The federal order to schedule brorphine became effective March 1, 2021, *Federal Register*, Volume 88, Number 38, pages 11862-11867; *https://www.govinfo.gov/content/pkg/FR-2021-03-01/pdf/2021-04242.pdf.*

III. ANALYSIS:

In accordance with 21 U.S.C. 811(h)(3) and based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of brorphine pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for brorphine in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for brorphine indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated September 22, 2020, notified the Assistant Secretary of DEA's intention to temporarily place brorphine in schedule I. DEA subsequently published a notice of intent on December 3, 2020.

The availability of synthetic opioids on the illicit drug market continues to pose an imminent hazard to the public safety. Adverse health effects associated with the abuse of synthetic opioids and the increased popularity of these substances have posed serious health concerns in recent years. The presence of new synthetic opioids with no approved medical use exacerbates the unprecedented opioid epidemic in the United States continues to experience. The trafficking and abuse of new synthetic opioids are deadly new trends. The identification of brorphine on the illicit drug market has been reported in the United States, Canada, Belgium, and Sweden. Data obtained from preclinical pharmacology studies show that brorphine has a pharmacological profile similar to that of other potent opioids such as morphine and fentanyl, schedule II controlled substances. Because of the pharmacological similarities between brorphine and other potent opioids, the use of brorphine presents a high risk of abuse and may negatively affect users and their communities. The positive identification of this substance in law enforcement seizures and post-mortem toxicology reports is a serious concern to the public safety. The abuse of brorphine has been associated with at least seven fatalities between June and July 2020 in the United States. Thus, brorphine poses an imminent hazard to public safety.

1) History and Current Pattern of Abuse

Brorphine is part of a structural class of compounds known as substituted piperidine benzimidazolones. The general synthesis of brorphine was first reported in the literature in 2018. Brorphine is not an approved pharmaceutical product and is not approved for medical use anywhere in the world. The Assistant Secretary, by a letter to DEA dated October 27, 2020, stated that there are no FDA-approved new drug applications ("NDAs") or investigational new drug applications ("INDs" for brorphine in the United States. Hence, DEA notes there is no legitimate channel for brorphine as a marketed drug product. The appearance of brorphine on the illicit drug market is similar to other designer drugs trafficked for their psychoactive effects. Since 2014, numerous synthetic opioids structurally related to fentanyl and several synthetic opioids from other structural classes have begun to emerge on the illicit drug market as evidenced by the identification of these drugs in forensic drug exhibits and toxicology samples. Beginning in June 2019, brorphine emerged in the United States illicit, synthetic drug market as evidenced by brorphine's identification in drug seizures. Authorities Between July and September 2019, brorphine was first reported in drug

casework in Canada and was first reported in police seizures in Sweden in March 2020. Brorphine has been encountered by United States law enforcement in powder form. In the United States, brorphine has been identified as a single substance and in combination with other substances. Between June 2019 and August 2020, there are twenty reports of brorphine in the National Forensic Laboratory Information System ("NFLIS") from three different states (see Scope, Duration, and Significance of Abuse). In several NFLIS encounters, brorphine was found in combination with heroin (a schedule I substance) and fentanyl (a schedule II substance). In reports from the Northeastern Illinois Regional Crime Laboratory, suspected heroin/fentanyl powders were analyzed and found to be brorphine in combination with flualprazolam, a non-scheduled benzodiazepine, and diphenhydramine, an over-the-counter antihistamine. Post-mortem toxicology samples collected and submitted to National Medical Services ("NMS") Laboratory in June and July 2020 verified the identification of brorphine. Brorphine was first reported by the Center for Forensic Science Research and Education ("CFSRE") – Novel Psychoactive Substance ("NPS") Discovery Program (under the novel psychoactive substances discovery program, in collaboration with NMS Labs) in July 2020. In seven post-mortem toxicology reports in June and July 2020, brorphine was found in combination with fentanyl, flualprazolam, and heroin. Evidence suggests that individuals are using brorphine as a replacement to heroin or other opioids, either knowingly or unknowingly.

2) Scope, Duration, and Significance of Abuse

Brorphine has been described as a potent synthetic opioid, and evidence suggests it is being abused for its opioidergic effects. According to a recent publication by CFSRE - NPS Discovery Program, brorphine has been positively identified in seven death investigation cases spanning between June and July 2020. These cases occurred in three states, Illinois with three (3) deaths, Minnesota with three (3) deaths, and Arizona with one (1) death. Most of the decedents were male. The decedents' ages ranged between their 40's and 60's with an average age of 52 years. Other substances identified in postmortem blood specimens obtained from these decedents include flualprazolam, a nonscheduled benzodiazepine (n = 5), fentanyl, a schedule II substance (n = 7), and heroin, a schedule I substance (n = 4). The appearance of benzodiazepines and other opioids is common with polysubstance abuse. NFLIS registered 20 reports of brorphine from Ohio (4 reports), Pennsylvania (1 report), and Wisconsin (15 reports) in 2019 and 2020. NFLIS was queried on August 18, 2020, for brorphine. Due to the rapid appearance of the drug, brorphine is most likely under reported as forensic laboratories secure reference standards for the confirmative identification and reporting of this substance. The population likely to abuse brorphine appears to be the same as those abusing prescription opioid analgesics, heroin, tramadol, fentanyl, and other synthetic opioid substances. This is evidenced by the types of other drugs co-identified in samples obtained from brorphine seizures and post-mortem toxicology reports. Because abusers of brorphine are likely to obtain it through unregulated sources, the identity, purity, and quantity of brorphine are uncertain and inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well-characterized. According to the most recent data from the National Survey on Drug Use and Health (NSDUH), as of 2019, an estimated 10.1 million people aged 12 years or older misused opioids in the past year, including 9.7 million prescription pain reliever misusers and 745,000 heroin users. In 2019, an estimated 1.6 million people had an opioid use disorder, which included 1.4 million people with a prescription pain reliever use disorder and 438,000 people with heroin use disorder. In 2018, an estimated 10.3 million people aged 12 years or older misused opioids in the past year, including 9.9 million prescription pain reliever misusers and 808,000 heroin users. In 2018, an estimated 2 million people had an opioid use disorder, which included 1.7 million people with a prescription pain reliever use disorder and 500,000 people with heroin use disorder. This population abusing opioids is likely to be at risk of abusing brorphine. Individuals who initiate use (i.e., use a drug for the first time) of brorphine are

likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (e.g., fentanyl, morphine, etc.). Law enforcement reports demonstrate that brorphine is being illicitly distributed and abused.

3) What, if Any, Risk There is to the Public Health

The increase in opioid overdose deaths in the United States has been exacerbated recently by the availability of potent synthetic opioids on the illicit drug market. Data obtained from pre-clinical studies demonstrate that brorphine exhibits a pharmacological profile similar to that of other mu-opioid receptor agonists. Data from in vitro studies showed that brorphine binds to and activates the mu-opioid receptors. In the [S]GTPγS cell-based receptor assay, brorphine, similar to fentanyl, acted as a mu-opioid receptor agonist. Brorphine's activation of the mu-opioid receptor was also shown to involve recruitment of beta-arrestin-2, a regulatory protein whose interaction with the mu-opioid receptor has been implicated in the adverse effects of mu-opioid receptor activation. Brorphine binds to and activates the mu-opioid receptor and has efficacy on scale with fentanyl in in vitro studies. It is well established that substances that act as mu-opioid receptor agonists have a high potential for addiction and can induce dose-dependent respiratory depression. As with any mu-opioid receptor agonist, the potential health and safety risks for users of brorphine are high. The public health risks associated to the abuse of heroin and other μ-opioid receptor agonists are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. According to the Centers for Disease Control and Prevention ("CDC"), opioids, mainly synthetic opioids other than methadone, are predominantly responsible for drug overdose deaths in recent years. A CDC report shows that, from 2013 to 2018, opioid-related overdose deaths in the United States increased from 25,052 to 46,802. Of the drug overdose deaths for 2018, opioids were involved in about 69.5 percent of all drug-involved overdose deaths. In the United States, the abuse of opioid analgesics has resulted in large numbers of treatment admissions, emergency department visits, and fatal overdoses. The introduction of potent synthetic opioids such as brorphine into the illicit market may serve as a portal to problematic opioid use for those seeking these powerful opioids. Brorphine has been co-identified with other substances in seven post-mortem toxicology cases in June and July 2020. These substances include other opioids such as fentanyl and heroin, and other substance classes such as benzodiazepines. These deaths occurred in three states: Illinois, Arizona, and Minnesota. Information gathered from case history findings shows that brorphine use is similar to that of classic opioid agonists. As documented by toxicology reports, poly-substance abuse remains common in fatalities associated with the abuse of brorphine.

IV. RECOMMENDATION:

The Acting Administrator of the Drug Enforcement Administration ("DEA") issued a temporary order to schedule 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2Hbenzo[d]imidazol-2-one (commonly known as brorphine), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act .

The Department recommends placing this substance in Schedule I in the same manner as the federal Drug Enforcement Administration and based on the finding by the Acting Administrator that the placement of brorphine in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the addition of brorphine 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2Hbenzo[d]imidazol-2-one, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act to include:

( ) Brorphine 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2H-benzo[d]imidazol-2-one, its isomers, esters, ethers, salts and salts of isomers, esters and ethers

Submitted by:

Lisa Thomson
Bureau Director
Bureau of Drug Control

Gwen Thompson
Deputy Director
Healthcare Quality

Attachment:
Federal Register, Volume 88, Number 38, pages 11862-11867, March 1, 2021

impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AWP CA D Palmdale, CA [Amended]

Palmdale USAF Plant 42 Airport, CA
(Lat. 34°37′46″ N, long. 118°05′04″ W)

That airspace extending upward from the surface to and including 5,000 feet MSL within a 4.3-mile radius of Palmdale USAF Plant 42 Airport. This Class D airspace area is effective during the specific dates and times established, in advance, by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AWP CA E4 Palmdale, CA [Amended]

Palmdale USAF Plant 42 Airport, CA
(Lat. 34°37′46″ N, long. 118°05′04″ W)

That airspace extending upward from the surface within 1 mile each side of the 270° bearing from the airport, extending from the 4.3-mile radius to 7.5 miles west of Palmdale USAF Plant 42 Airport. This Class E airspace area is effective during the specific dates and times established, in advance, by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AWP CA E5 Palmdale, CA [Amended]

Palmdale USAF Plant 42 Airport, CA
(Lat. 34°37′46″ N, long. 118°05′04″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the airport, and within 6.1 miles each side of the 080° bearing from the airport, extending from the 6.8-mile radius to 12.9 miles east of the airport, and within 4 miles north and 8 miles south of the 086° bearing from the airport, extending from the airport to 14.3 miles east of the airport, and within 2 miles each side of the 274° bearing from the airport, extending from the 6.8-mile radius to 13.4 miles west of Palmdale USAF Plant 42 Airport.

Issued in Seattle, Washington, on February 16, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–03904 Filed 2–26–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–716]

Schedules of Controlled Substances: Temporary Placement of Brorphine in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this temporary order to schedule 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2*H*-benzo[*d*]imidazol-2-one (commonly known as brorphine), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act . This action is based on a finding by the Acting Administrator that the placement of brorphine in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle brorphine.

DATES: This temporary scheduling order is effective March 1, 2021, until March 1, 2023. If this order is extended or made permanent, DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) provides the Attorney General (as delegated to the Administrator of Drug Enforcement Administrator (DEA) pursuant to 28 CFR 0.100) with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled [1] under section 811(h), the Administrator may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308.

Background

The CSA requires the Administrator to notify the Secretary of the

[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this document adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

Department of Health and Human Services (HHS) of his intention to temporarily place a substance in schedule I.[2] 21 U.S.C. 811(h)(4). The Acting Administrator transmitted such notice regarding brorphine to the Assistant Secretary for Health of HHS (Assistant Secretary) by letter dated September 22, 2020. The Assistant Secretary responded to this notice by letter dated October 27, 2020, and advised that based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for brorphine. The Assistant Secretary also stated that HHS had no objection to the temporary placement of brorphine in schedule I of the CSA.

DEA has taken into consideration the Assistant Secretary's comments as required by subsection 811(h)(4). Brorphine is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for brorphine under 21 U.S.C. 355. DEA has found that the control of brorphine in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent to temporarily schedule brorphine on December 3, 2020. 85 FR 78047. That notice of intent discussed findings from DEA's three-factor analysis dated August 2020, which DEA made available on *www.regulations.gov.*

To find that placing a substance temporarily in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse diversion from legitimate channels; and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

[2] The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

Available data and information for brorphine summarized below indicate that it has high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. DEA's August 2020 three-factor analysis and the Assistant Secretary's October 27, 2020, letter are available in their entirety under the tab "Supporting Documents" of the public docket of this action at *www.regulations.gov.*

Brorphine

The availability of synthetic opioids on the illicit drug market continues to pose an imminent hazard to the public safety. Adverse health effects associated with the abuse of synthetic opioids and the increased popularity of these substances have posed serious health concerns in recent years. The presence of new synthetic opioids with no approved medical use exacerbates the unprecedented opioid epidemic in the United States continues to experience. The trafficking and abuse of new synthetic opioids are deadly new trends.

The identification of brorphine on the illicit drug market has been reported in the United States, Canada, Belgium, and Sweden. Data obtained from preclinical pharmacology studies show that brorphine has a pharmacological profile similar to that of other potent opioids such as morphine and fentanyl, schedule II controlled substances. Because of the pharmacological similarities between brorphine and other potent opioids, the use of brorphine presents a high risk of abuse and may negatively affect users and their communities. The positive identification of this substance in law enforcement seizures and post-mortem toxicology reports is a serious concern to the public safety. The abuse of brorphine has been associated with at least seven fatalities between June and July 2020 in the United States. Thus, brorphine poses an imminent hazard to public safety.

Available data and information for brorphine, as summarized below, indicates that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. DEA's three-factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at *www.regulations.gov* under Docket Number DEA–716.

Factor 4. History and Current Pattern of Abuse

Brorphine is part of a structural class of compounds known as substituted piperidine benzimidazolones. The general synthesis of brorphine was first reported in the literature in 2018. Brorphine is not an approved pharmaceutical product and is not approved for medical use anywhere in the world. The Assistant Secretary, by a letter to DEA dated October 27, 2020, stated that there are no FDA-approved NDAs or INDs for brorphine in the United States. Hence, DEA notes there is no legitimate channel for brorphine as a marketed drug product. The appearance of brorphine on the illicit drug market is similar to other designer drugs trafficked for their psychoactive effects.

Since 2014, numerous synthetic opioids structurally related to fentanyl and several synthetic opioids from other structural classes have begun to emerge on the illicit drug market as evidenced by the identification of these drugs in forensic drug exhibits and toxicology samples. Beginning in June 2019, brorphine emerged in the United States illicit, synthetic drug market as evidenced by brorphine's identification in drug seizures. Authorities Between July and September 2019, brorphine was first reported in drug casework in Canada and was first reported in police seizures in Sweden in March 2020.[3]

Brorphine has been encountered by United States law enforcement in powder form. In the United States, brorphine has been identified as a single substance and in combination with other substances. Between June 2019 and August 2020, there are twenty reports of brorphine in the National Forensic Laboratory Information System (NFLIS) from three different states (see Factor 5).[4] In several NFLIS encounters, brorphine was found in combination

[3] Health Canada Drug Analysis Service (2019); Analyzed Drug Report Canada 2019—Q3 (July to September); European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) (2020); EU Early Warning System Situation Report, Situation report 1—June 2020.

[4] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is currently 98.5 percent. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, December 12, 2011. NFLIS data was queried on August 18, 2020.

with heroin (a schedule I substance) and fentanyl (a schedule II substance). In reports from the Northeastern Illinois Regional Crime Laboratory, suspected heroin/fentanyl powders were analyzed and found to be brorphine in combination with flualprazolam, a non-scheduled benzodiazepine, and diphenhydramine, an over-the-counter antihistamine.[5]

Post-mortem toxicology samples collected and submitted to National Medical Services (NMS) Laboratory[6] in June and July 2020 verified the identification of brorphine. Brorphine was first reported by the Center for Forensic Science Research and Education (CFSRE)—Novel Psychoactive Substance (NPS) Discovery Program (under the novel psychoactive substances discovery program, in collaboration with NMS Labs) in July 2020. In seven post-mortem toxicology reports in June and July 2020, brorphine was found in combination with fentanyl, flualprazolam, and heroin. Evidence suggests that individuals are using brorphine as a replacement to heroin or other opioids, either knowingly or unknowingly.

Factor 5. Scope, Duration, and Significance of Abuse

Brorphine has been described as a potent synthetic opioid, and evidence suggests it is being abused for its opioidergic effects (see Factor 6). According to a recent publication by CFSRE—NPS Discovery Program, brorphine has been positively identified in seven death investigation cases spanning between June and July 2020. These cases occurred in three states—Illinois (3), Minnesota (3), and Arizona (1). Most (n=6) of the decedents were male. The decedents' ages ranged between 40's and 60's with an average age of 52 years. Other substances identified in postmortem blood specimens obtained from these decedents include flualprazolam, a nonscheduled benzodiazepine (n=5), fentanyl, a schedule II substance (n=7), and heroin, a schedule I substance (n=4). The appearance of benzodiazepines and other opioids is common with polysubstance abuse.

NFLIS registered 20 reports of brorphine from Ohio (4), Pennsylvania (1), and Wisconsin (15) in 2019 and 2020. NFLIS was queried on August 18, 2020, for brorphine. Due to the rapid appearance of the drug, brorphine is most likely under reported as forensic laboratories secure reference standards for the confirmative identification and reporting of this substance.

The population likely to abuse brorphine appears to be the same as those abusing prescription opioid analgesics, heroin, tramadol, fentanyl, and other synthetic opioid substances. This is evidenced by the types of other drugs co-identified in samples obtained from brorphine seizures and post-mortem toxicology reports. Because abusers of brorphine are likely to obtain it through unregulated sources, the identity, purity, and quantity of brorphine are uncertain and inconsistent, thus posing significant adverse health risks to the end user. The misuse and abuse of opioids have been demonstrated and are well-characterized. According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[7] as of 2019, an estimated 10.1 million people aged 12 years or older misused opioids in the past year, including 9.7 million prescription pain reliever misusers and 745,000 heroin users. In 2019, an estimated 1.6 million people had an opioid use disorder, which included 1.4 million people with a prescription pain reliever use disorder and 438,000 people with heroin use disorder. In 2018, an estimated 10.3 million people aged 12 years or older misused opioids in the past year, including 9.9 million prescription pain reliever misusers and 808,000 heroin users. In 2018, an estimated 2 million people had an opioid use disorder, which included 1.7 million people with a prescription pain reliever use disorder and 500,000 people with heroin use disorder. This population abusing opioids is likely to be at risk of abusing brorphine. Individuals who initiate use (*i.e.*, use a drug for the first time) of brorphine are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.*, fentanyl, morphine, etc.). Law enforcement reports demonstrate that brorphine is being illicitly distributed and abused.

Factor 6. What, if Any, Risk There Is to the Public Health

The increase in opioid overdose deaths in the United States has been exacerbated recently by the availability of potent synthetic opioids on the illicit drug market. Data obtained from pre-clinical studies demonstrate that brorphine exhibits a pharmacological profile similar to that of other mu-opioid receptor agonists. Data from *in vitro* studies showed that brorphine binds to and activates the mu-opioid receptors. In the [^{35}S]GTPγS cell-based receptor assay, brorphine, similar to fentanyl, acted as a mu-opioid receptor agonist. Brorphine's activation of the mu-opioid receptor was also shown to involve recruitment of beta-arrestin-2, a regulatory protein whose interaction with the mu-opioid receptor has been implicated in the adverse effects of mu-opioid receptor activation. Brorphine binds to and activates the mu-opioid receptor and has efficacy on scale with fentanyl in *in vitro* studies. It is well established that substances that act as mu-opioid receptor agonists have a high potential for addiction and can induce dose-dependent respiratory depression.

As with any mu-opioid receptor agonist, the potential health and safety risks for users of brorphine are high. The public health risks associated to the abuse of heroin and other μ-opioid receptor agonists are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids other than methadone, are predominantly responsible for drug overdose deaths in recent years. A CDC report shows that, from 2013 to 2018, opioid-related overdose deaths in the United States increased from 25,052 to 46,802. Of the drug overdose deaths for 2018, opioids were involved in about 69.5 percent of all drug-involved overdose deaths.

In the United States, the abuse of opioid analgesics has resulted in large numbers of treatment admissions, emergency department visits, and fatal overdoses. The introduction of potent synthetic opioids such as brorphine into

[5] Email communications with Northeastern Illinois Regional Crime Laboratory, dated 7/1/2020 and 6/11/2020.

[6] NMS Labs, in collaboration with the Center for Forensic Science Research and Education at the Fredric Rieders Family Foundation and the Organized Crime Drug Enforcement Task Force at the United States Department of Justice, has received funding from the Centers for Disease Control and Prevention to develop systems for the early identification and notification of novel psychoactive substances in the drug supply within the United States.

[7] NSDUH, formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (*i.e.*, ever used), past year, and past month abuse or dependence.

the illicit market may serve as a portal to problematic opioid use for those seeking these powerful opioids.

Brorphine has been co-identified with other substances in seven post-mortem toxicology cases in June and July 2020. These substances include other opioids such as fentanyl and heroin, and other substance classes such as benzodiazepines. These deaths occurred in three states: Illinois, Arizona, and Minnesota. Information gathered from case history findings shows that brorphine use is similar to that of classic opioid agonists. As documented by toxicology reports, poly-substance abuse remains common in fatalities associated with the abuse of brorphine.

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of brorphine pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for brorphine in the United States.[8] A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for brorphine indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by 21 U.S.C. 811(h)(4), the Acting Administrator, through a letter dated September 22, 2020, notified the Assistant Secretary of DEA's intention to temporarily place brorphine in schedule I. DEA subsequently published a notice of intent on December 3, 2020. 85 FR 78047.

Conclusion

In accordance with 21 U.S.C. 811(h)(1) and (3), the Acting Administrator considered available data and information, herein set forth the grounds for his determination that it is necessary to temporarily schedule brorphine in schedule I of the CSA and finds that placement of this substance in schedule I of the CSA is necessary in order to avoid an imminent hazard to the public safety.

This temporary order scheduling this substance will be effective on the date the order is published in the **Federal Register** and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this temporary order, brorphine will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, brorphine must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312, as of March 1, 2021. Any person who currently handles brorphine, and is not registered with DEA, must submit an application for registration and may not continue to handle brorphine as of March 1, 2021, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after March 1, 2021 is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle brorphine must surrender all currently held quantities of brorphine.

3. *Security.* Brorphine is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b) and in accordance with 21 CFR 1301.71–1301.93, as of March 1, 2021. Non-practitioners handling brorphine must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of brorphine must be in compliance with 21 U.S.C. 825, 958(e) and be in accordance with 21 CFR part 1302. Current DEA registrants will have 30 calendar days from March 1, 2021 to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of brorphine on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants will have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including brorphine) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to brorphine, pursuant to 21 U.S.C. 827

[8] Although there is no evidence suggesting that brorphine has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

i. The drug's chemistry must be known and reproducible;

ii. there must be adequate safety studies;

iii. there must be adequate and well-controlled studies proving efficacy;

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

and 958 and in accordance with 21 CFR parts 1304, 1312, and 1317, and section 1307.11. Current DEA registrants authorized to handle brorphine shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute brorphine must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of March 1, 2021.

8. *Order Forms.* All DEA registrants who distribute brorphine must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of March 1, 2021.

9. *Importation and Exportation.* All importation and exportation of brorphine must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of March 1, 2021.

10. *Quota.* Only DEA registered manufacturers may manufacture brorphine in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of March 1, 2021.

11. *Liability.* Any activity involving brorphine not authorized by, or in violation of the CSA, occurring as of March 1, 2021, is unlawful and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

The CSA provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). As provided in this subsection, the Administrator (as delegated by the Attorney General) by order may schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this temporary scheduling order. The APA expressly differentiates between an order and a rule, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*'' 5 U.S.C. 551(6) (emphasis added). The specific language chosen by Congress indicates an intention for DEA to proceed through the issuance of an *order* instead of proceeding by rulemaking. Given that Congress specifically requires the Administrator to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), note that in 21 U.S.C. 811(h)(1), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Alternatively, even if this action was subject to section 553 of the APA, the Acting Administrator finds that there is good cause to forgo the notice-and-comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Although DEA believes this temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Acting Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable here, as DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866.

This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (h)(49) to read as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

(49) 1-[1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2*H*-benzo[*d*]imidazol-2-one, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: brorphine; 1-[1-[1-(4-bromophenyl)ethyl]-4-piperidinyl]-1,3-dihydro-2*H*-benzimidazol-2-one) 9098

* * * * *

D. Christopher Evans,
Acting Administrator.
[FR Doc. 2021–04242 Filed 2–26–21; 8:45 am]
BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2019–0613; FRL–10019–20–Region 4]

Air Plan Approval; North Carolina: Revisions to Annual Emissions Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of North Carolina, through the North Carolina Department of Environmental Quality, Division of Air Quality (DAQ), on July 10, 2019. The SIP revision modifies the State's annual emissions reporting regulation by removing the annual emissions reporting requirement for certain non-Title V facilities in geographic areas that have been redesignated to attainment for the 1979 1-hour ozone national ambient air quality standards ("NAAQS" or "standards") and in the areas listed in the rule that have been redesignated to attainment for the 1997 8-hour ozone NAAQS, with the exception of the geographic areas that have been redesignated to attainment for the 2008 8-hour ozone NAAQS. The SIP revision also makes minor changes that do not significantly alter the meaning of the regulation. EPA is approving this revision pursuant to the Clean Air Act (CAA or Act).

DATES: This rule is effective March 31, 2021.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2019–0613. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials can either be retrieved electronically via *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that, if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9088. Ms. Bell can also be reached via electronic mail at *bell.tiereny@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1979, EPA promulgated a NAAQS for ozone, setting the standard at 0.12 parts per million (ppm) averaged over a 1-hour time frame. *See* 44 FR 8202 (February 8, 1979). In 1997, EPA promulgated a revised NAAQS for ozone, setting the standard at 0.08 ppm averaged over an 8-hour time frame. *See* 62 FR 38856 (July 18, 1997).[1] In 2008, EPA revised the level of the 8-hour ozone standard to 0.075 ppm. *See* 73 FR 16436 (March 27, 2008).[2] The promulgation of a new or revised NAAQS triggers a CAA requirement for EPA to designate as nonattainment any area that violates the NAAQS or contributes to a violation in a nearby area. On November 6, 1991, EPA published designations and classifications for the 1979 1-hour ozone NAAQS.[3] *See* 56 FR 56694. EPA initially published designations and classifications for the revised 1997 8-hour and revised 2008 8-hour ozone standards on April 30, 2004 (69 FR 23858) and May 21, 2012 (77 FR 30088), respectively. The geographic areas designated as nonattainment in North Carolina for the 1997 8-hour ozone standard included the Charlotte-Gastonia-Rock Hill, NC-SC Area (the North Carolina portion is hereinafter the "1997 Charlotte Area").[4] The geographic areas designated as nonattainment in North Carolina for the 2008 ozone standard are part of an area known as the Charlotte-Rock Hill, NC-SC Area (the North Carolina portion is hereinafter the "2008 Charlotte Area").[5] EPA redesignated North Carolina's 1979 ozone nonattainment areas to attainment in a series of actions from 1993 to 1995,[6] redesignated the 1997 Charlotte Area to attainment on December 2, 2013 (78 FR 72036), and redesignated the 2008 Charlotte Area to attainment on July 28, 2015 (80 FR 44873).

North Carolina was required to develop nonattainment SIP revisions addressing the CAA requirements for its ozone nonattainment areas. Among other things, North Carolina was required to address the annual emissions reporting requirement in CAA section 182(a)(3)(B), which requires each state with an ozone nonattainment area to submit a SIP revision requiring stationary sources that emit 25 tons per year (tpy) or more of nitrogen oxides (NO_X) or volatile organic compounds (VOC) within the nonattainment area to provide certified annual emissions statements to the state showing actual annual NO_X and VOC emissions from the sources.

[1] EPA has revoked the 1979 and 1997 ozone standards. *See* 69 FR 23951 (April 30, 2004) and 80 FR 12264 (March 6, 2015), respectively.

[2] EPA revised the level of the 8-hour ozone standard to 0.070 ppm in 2015 and designated the entire state as attainment/unclassifiable for that NAAQS in 2017. *See* 80 FR 65296 (October 22, 2015) and 82 FR 54232 (November 16, 2017).

[3] EPA designated the following geographic areas in North Carolina as nonattainment for the 1979 ozone standard: Davidson, Durham, Forsyth, Gaston, Guilford, Mecklenburg, and Wake Counties, the Dutchville Township in Granville County, and that part of Davie County bounded by the Yadkin River, Dutchmans Creek, North Carolina Highway 801, Fulton Creek and back to the Yadkin River.

[4] The geographic areas designated as nonattainment in North Carolina for the 1997 ozone standard included all geographic areas designated as nonattainment for the 1979 ozone standard as well as additional areas. The 1997 Charlotte Area consists of Cabarrus, Gaston, Lincoln, Mecklenburg, Rowan, and Union Counties and Davidson Township and Coddle Creek Township in Iredell County.

[5] The 2008 Charlotte Area is a subset of the 1997 Charlotte Area and consists of Central Cabarrus Township, Concord Township, Georgeville Township, Harrisburg Township, Kannapolis Township, Midland Township, Mount Pleasant Township, New Gilead Township, Odell Township, Poplar Tent Township, and Rimertown Township in Cabarrus County; Crowders Mountain Township, Dallas Township, Gastonia Township, Riverbend Township, and South Point Township in Gaston County; Davidson Township and Coddle Creek Township in Iredell County; Catawba Springs Township, Ironton Township, and Lincolnton Township in Lincoln County; Atwell Township, China Grove Township, Franklin Township, Gold Hill Township, Litaker Township, Locke Township, Providence Township, Salisbury Township, Steele Township, and Unity Township in Rowan County; and Goose Creek Township, Marshville Township, Monroe Township, Sandy Ridge Township, and Vance Township in Union County.

[6] *See* 58 FR 47391 (November 9, 1993), 59 FR 18300 (April 18, 1994), and 60 FR 34859 (July 5, 1995).

Date: March 11, 2021

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

From: Bureau of Environmental Health Services

Re: Public Hearing for Notice of Final Regulation Amending R.61-34, *Raw Milk for Human Consumption*, and R.61-34.1, *Pasteurized Milk and Milk Products*, Document No. 5033

I. Introduction

The Bureau of Environmental Health Services ("Bureau") proposes the attached Notice of Final Regulation amending R.61-34, *Raw Milk for Human Consumption*, and R.61-34.1, *Pasteurized Milk and Milk Products*. 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, S.C. Code Section 44-1-150 allows for the enforcement of these regulations. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

II. Facts

1. Pursuant to R.61-34, *Raw Milk for Human Consumption*, the Department provides sanitation oversight for the production and sale of raw milk that has not been pasteurized for food safety in South Carolina. The Bureau is amending R.61-34 to address the further processing and sale of raw milk products, specifically, cream, buttermilk, and kefir, and adding additional consumer advisory changes that are needed for products that receive further processing or become necessary as a byproduct of further processing. The revisions also update raw milk standards as needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance ("PMO").

2. Pursuant to R.61-34.1, *Pasteurized Milk and Milk Products*, the Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Bureau is amending R.61-34.1 to adopt requirements of the 2019 PMO. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of R.61-34.1 to incorporate the updated requirements of the 2019 PMO will enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Bureau further provides clarification of requirements for potable water sources.

3. The Bureau is also revising R.61-34 and R.61-34.1 for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvements. The amendments to both regulations also include updates to administrative and enforcement provisions.

4. The Department had a Notice of Drafting published in the March 27, 2020, *State Register*.

5. Appropriate Department staff conducted an internal review of the proposed amendments on December 3, 2020.

6. The Bureau conducted two separate stakeholder engagement meetings on December 7, 2020. The first meeting for R.61-34.1 had five (5) stakeholders in attendance, and the second meeting for R.61-34 had

twenty-one (21) stakeholders in attendance. Comments made in these meetings included support for the amendments, suggestions for terminology, and discussion of the scope of raw milk products addressed in R.61-34. The Bureau considered these comments and, where appropriate, incorporated them into the proposed regulations.

7. Upon receiving approval during the January 7, 2021, Board meeting, the Bureau had a Notice of Proposed Regulation published in the January 22, 2021, *State Register*. The Department received public comments from five people by the February 22, 2021, close of the public comment period. Attachment B presents a summary of these public comments received and Department responses.

8. The Bureau conducted two additional, separate stakeholder engagement meetings on February 12, 2021, following publication of the Notice of Proposed Regulation. The first meeting for R.61-34.1 had nine (9) stakeholders in attendance, and the second meeting for R.61-34 had fourteen (14) stakeholders in attendance. Comments made in these meetings included several requests to add kefir as an allowed raw milk product under R.61-34.

9. After consideration of all timely received comments, staff made substantive changes to the R.61-34 regulatory text of the Notice of Proposed Regulation approved by the Board in the January 7, 2021, Board meeting and published in the January 22, 2021, *State Register*. Descriptions of the changes appear in Attachment B, Summary of Public Comments and Department Responses.

10. Our stakeholders have continued to express appreciation for the Department's industry engagement and support for these revisions.

III. Request for Approval

The Bureau of Environmental Health Services respectfully requests the Board to find need and reasonableness of the attached amendment of R.61-34, *Raw Milk for Human Consumption*, and R.61-34.1, *Pasteurized Milk and Milk Products*, for submission to the General Assembly.

Renee G. Shealy
Bureau Chief

Myra C. Reece
Director

Attachments:
A. Notice of Final Regulation
B. Summary of Public Comments and Department Responses

ATTACHMENT A

STATE REGISTER NOTICE OF FINAL REGULATION
FOR R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk Products

March 11, 2021

Document No. 5033
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-1-140(3) and 44-1-150

61-34. Raw Milk for Human Consumption.
61-34.1. Pasteurized Milk and Milk Products.

Synopsis:

Pursuant to R.61-34, Raw Milk for Human Consumption, the Department of Health and Environmental Control ("Department") provides sanitation oversight for the production and sale of raw milk that has not been pasteurized for food safety in South Carolina. The Department is amending R.61-34 to address the further processing and sale of raw milk products, specifically, cream, buttermilk, and kefir, and to add additional consumer advisory changes that would be needed for products that receive further processing or become necessary as a byproduct of further processing. The revisions also update raw milk standards as needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance ("PMO").

Pursuant to R.61-34.1, Pasteurized Milk and Milk Products, the Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Department is adopting requirements of the 2019 PMO through the amendment of R.61-34.1. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of R.61-34.1 to incorporate the updated requirements of the 2019 PMO will enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Department further provides clarification of requirements for potable water sources.

The Department is also revising R.61-34 and R.61-34.1 for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvements. The amendments to both regulations also include updates to administrative and enforcement provisions.

The Department had a Notice of Drafting published in the March 27, 2020, *South Carolina State Register*.

Instructions:

Replace R.61-34 and R.61-34.1 in their entirety with these amendments.

Text:

~~Indicates Matter Stricken~~
Indicates New Matter

61-34. Raw Milk for Human Consumption.

(Statutory Authority: S.C. Code Sections 44-1-140(3) and 44-1-150)

Table of Contents

SECTION I. Definitions and Standards.

A. The following definitions shall apply in the interpretation and the enforcement of this Regulation:

1. ~~ABNORMALITIES OF MILK~~Abnormalities of Milk means

a. Abnormal Milk: Milk that is visibly changed in color, odor, and/or texture.

b. Undesirable Milk: Milk that, prior to the milking of the animal, is known to be unsuitable for sale, such as colostrum.

c. Contaminated Milk: Milk that is not sellable or is unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements or treatment with medicines or insecticides not approved for use on dairy animals by the United States Food and Drug Administration (FDA) or the United States Environmental Protection Agency (EPA).

2. Adulterated: means raw milk or raw milk products are deemed to be adulterated if the product:

a. Bears or contains any poisonous or deleterious substance in a quantity that may render it injurious to health;

b. Bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by state or federal regulation, or is in excess of such tolerance if one has been established;

c. Consists, in whole or in part, of any substance unfit for human consumption;

d. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;

e. 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;

f. 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;

g. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 342); or

h. Contains any animal drug residues.

~~2~~3. ~~AUTOMATIC MILKING INSTALLATION~~Automatic Milking Installation (AMI) means the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning, and sanitation.

4. Buttermilk means a cultured dairy product that is produced by culturing milk or cream with characterizing microbial organisms and which contains at least 3.25% milkfat and at least 8.25% milk solids not fat.

~~3~~5. ~~CLEAN~~Clean means ~~direct product contact surfaces that have had~~ the effective and thorough removal of product and/or contaminants from direct product contact surfaces.

~~4~~6. ~~CODE OF FEDERAL REGULATIONS~~ Code of Federal Regulations (CFR) means the current Code of Federal Regulations.

~~5~~7. ~~COMMON NAME~~Common Name means the generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, etc.

~~6. COOLING POND a man-made structure designed for the specific purpose of cooling cows.~~

8. Craft Usage means the use of raw milk to create products such as soap, candles, or other non-edible products.

9. Cream means a dairy product that is composed of the higher-fat layer separated from the top of milk and which contains at least 18% milkfat.

~~7~~10. ~~DAIRY FARM~~Dairy Farm means any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, or other hooved mammals) are kept for milking purposes and from which a part or all of the milk or milk products ~~is~~are provided, sold, or offered for sale.

~~8~~11. ~~DEPARTMENT~~Department means the South Carolina Department of Health and Environmental Control and its representatives.

~~9~~12. ~~DRUG~~Drug means:

a. ~~articles~~A substance recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them;

b. ~~articles intended for use~~A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease~~ in man or other animals~~;

c. ~~articles~~A substance (other than food) intended to affect the structure or any function of the body ~~of man or other animals~~; and

d. ~~articles~~A substance intended for use as a component of ~~any articles~~ a substance specified in clause a, b, or c but does not include devices or their components, parts, or accessories.

~~10~~13. ~~GOAT MILK~~Goat Milk means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this Regulation.

14. Kefir means a cultured dairy product that is produced by fermentation of milk by Lactobacillus bulgaricus, Lactobacillus acidophilus, and Lactobacillus caucasicus and which contains not less than 3.5% milk fat or, if made from goat milk, not less than 2.8% milkfat.

~~11~~15. ~~MILK~~Milk means the normal lacteal secretion of hooved mammals, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Regulation. Hooved mammals milk shall include bovine milk, goat milk, sheep milk, ~~and~~ water buffalo milk, etc.

~~12~~16. ~~MILK~~ ~~DISTRIBUTOR~~ Milk or Milk Products Distributor means any person who offers for sale milk or milk products that ~~has~~ have been packaged at ~~the same~~a permitted location ~~that it was produced~~.

17. Milk or Milk Products Plant means any place, premises, or establishment where milk or milk products are collected, handled, processed, and stored or prepared for distribution.

~~13~~18. ~~MILK~~ ~~PRODUCER~~Milk or Milk Products Producer means any person who operates a dairy farm and provides, sells, or offers milk or milk products for sale that ~~was~~were produced at the farm.

~~14~~19. ~~MISBRANDED MILK~~Misbranded Milk or Milk Product means any milk or milk product ~~deemed to be misbranded~~ when:

a. ~~t~~The product's container bears or accompanies any false or misleading written, printed, or graphic matter;

b. ~~t~~The milk or milk product does not conform to the definitions as contained in this Regulation; ~~and~~or

c. ~~t~~The product is not labeled in accordance with this Regulation.

~~15~~20. ~~OFFICIALLY DESIGNATED LABORATORY~~Officially Designated Laboratory means 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 SC Grade A raw milk and raw milk products for human consumption and commingled milk tank truck samples of raw milk and raw milk products for drug residues and bacterial limits.

~~16~~21. ~~PERSON~~Person means any individual, producer, distributor, plant operator, partnership, corporation, company, firm, trustee, association, or institution.

22. Raw Milk means milk that has not received any heat treatment such as pasteurization or any other further processing.

23. Raw Milk Products means unpasteurized buttermilk, kefir, or cream.

24. Risk means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

~~17~~25. ~~SANITIZATION~~Sanitization means 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 practical. 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.

~~18~~26. ~~SHEEP MILK~~Sheep Milk means the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this Regulation.

~~19~~27. ~~WATER BUFFALO MILK~~Water Buffalo Milk means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this Regulation.

B. Standards.

All ~~Grade "A"~~ raw milk and raw milk products for human consumption shall be bottled, packaged, and sealed at the same location where ~~it was~~they were produced, or, in the case of raw milk products, at a location under the direct control of the raw milk producer that has been approved by the Department, and ~~it~~ all raw milk and raw milk products shall conform to the chemical, physical, bacteriological, and temperature standards ~~and~~as well as the sanitation requirements of this Regulation.

SECTION II. Adulterated or Misbranded Raw Milk or Raw Milk Products.

A. No person shall, within ~~the State of~~ South Carolina or its jurisdiction, produce, provide, sell, offer, barter, or expose for sale, or have in possession with intent to sell any raw milk or raw milk product that is adulterated or misbranded.

B. Any adulterated or misbranded raw milk or raw milk product may be impounded by the Department and disposed of in accordance with applicable laws or regulations.

C. ~~Milk~~ Raw milk and raw milk products ~~shall~~will be examined by the Department ~~as often as necessary~~in the course of routine or complaint inspections, outbreak investigations, or as otherwise deemed appropriate by the Department to determine that ~~it is~~ they are not adulterated or misbranded. The Department may, upon written notice to the owner or person in charge, place a hold order on any raw milk or raw milk product that it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, raw milk and raw milk products 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 raw milk or raw milk products by the Department, and neither such raw milk or raw milk products nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the Department except ~~on~~if ordered by a court of competent jurisdiction.

D. Adding water to raw milk will be considered a violation of this Regulation if the raw milk contains in excess of three percent (3%) water. A cryoscope shall be used to determine percentage of water by measuring the freezing point of the raw milk. When the freezing point of raw milk is greater than ~~31~~32.945°F~~.~~ (-0.525°C~~.~~), the farm shall be notified that ~~apparently~~ the raw milk apparently contains added water. If a second violation of this freezing point standard occurs within two (2) years, ~~an observed~~ milking or ~~operation of~~ processing operations ~~shall~~may be observed, ~~conducted~~ and samples will be collected and analyzed. The freezing point obtained from raw milk collected during the observation shall be used to determine a definite freezing point standard from the ~~individual~~ farm. A violation of the determined freezing point standard for a specific operation by over three (3%) percent within two (2) years of setting the standard for the individual farm shall call for a two (2) calendar day permit suspension or equivalent.

~~E. A cryoscope shall be used to determine adulteration by water.~~

~~F~~E. When raw milk or raw milk products ~~is~~ are found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, ~~it~~ they shall be ~~impounded~~ placed under a hold order and additional samples analyzed. ~~Milk~~ Raw milk or raw milk products found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals raw milk or raw milk products are positive for drug ~~resi dues~~residues, the raw milk or raw milk products shall be disposed of in a manner that removes it from the human or animal food chain. The Department shall immediately suspend the producer's SC Grade "A" permit, or equally effective measures shall be taken, to prevent the sale or distribution of raw milk or raw milk products containing drug residues, and a penalty shall be imposed. Future sales or distribution are prohibited until subsequent testing reveals the raw milk or raw milk products ~~is~~ are free of drug residue. The SC Grade "A" producer's permit may be reinstated to allow the sale or distribution of raw milk or raw milk products ~~for human food~~ when a representative sample taken by the Department from the producer's raw milk or raw milk products is no longer positive for drug residue. Whenever a drug residue test is positive, a recall shall be initiated, and an investigation shall be made to determine the cause. The farm inspection must be completed by the Department to determine the cause of the residue and actions that need to be taken to prevent future violations, including on-farm changes in procedures necessary to prevent future occurrences ~~as recommended by the Department~~.

SECTION III. Permits.

A. It shall be unlawful for any person who does not possess a permit from the Department to manufacture, bring into, send into, or receive into South Carolina or its jurisdiction, have in storage, sell, barter, or offer for sale therein, or offer to give away any raw milk or raw milk products defined in this Regulation, including but not limited to raw milk for craft usage.

B. Raw milk and raw milk products that have been manufactured under the provisions of this Regulation may be further distributed or sold at retail locations in South Carolina by distributors and retailers. Distributors and retailers are not required to have a permit, provided that the product has not been repackaged or relabeled.

C. Although distributors and retailers listed in Section III.B do not require a permit, the Department retains the authority to conduct an investigation in response to a complaint. The Department may require corrective action and issue orders as deemed necessary in response to food safety or health risks identified during the investigation.

~~B~~D. Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain ~~such~~ a permit. Permits shall not be transferable to other persons and/or locations or used by a person other than the permit holder.

~~C~~E. Every ~~milk~~ producer ~~and distributor~~ of raw milk or raw milk products for human consumption shall hold a valid permit issued by the Department prior to beginning operation. No permit shall be issued until all parts of the operation meet the requirements of this Regulation.

F. The production, distribution, storage, and sale of unpasteurized milk products other than the raw milk products defined in this Regulation (unpasteurized buttermilk, kefir, and cream) are prohibited in South Carolina and will be considered to be violations of this Regulation, except that aged raw milk cheese may be produced in accordance with the provisions of R.61-36, Manufactured Grade Dairy Products.

G. The addition of flavoring or other ingredients to raw milk or raw milk products other than cultures, citric acid, or salt needed for the processing of buttermilk and kefir is prohibited; provided, kefir may also contain harmless edible stabilizers subject to the limitations in VIII.C of this Regulation.

~~D~~H. The Department may deny a permit to produce, distribute or sell raw milk or raw milk products for human consumption when the applicant or facility has a history of ~~difficulty in complying~~noncompliance with other standards, regulations, or statutes governing milk and milk products.

~~SECTION IV. Labeling.~~

~~A. All bottles, containers, and packages enclosing raw milk for human consumption shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act (NLEA) of 1990 and regulations developed thereunder, the Code of Federal Regulations, and in addition shall comply with the applicable requirements of this section.~~

~~B. All bottles, containers, and packages enclosing raw milk for human consumption shall be conspicuously marked with:~~

~~1. the words "Grade A Raw" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.~~

~~2. the identity of the farm where packaged. This identity shall include the name, address, and the Department Permit Number.~~

~~3. the following information statement, in print no smaller than six (6) point font, shall be included on the package: This is a raw milk product that is not pasteurized.~~

~~4. the common name of the hooved mammal producing the milk shall precede the name of the milk when the product is made from other than cattle's milk. As an example, "Goat," "Sheep," "Water Buffalo," or "Other Hooved Mammal" milk respectively.~~

~~C. The Department shall not permit the use of any misleading marks, words, or endorsements upon the label. The Department may permit the use of registered trade designs or similar terms on the bottle cap or label, when, in its opinion, they are not misleading and are not used to obscure the labeling required by the Regulation. Descriptive labeling terms such as must not be used in conjunction with the Grade "A" designation or name of the raw milk and must not be false or misleading.~~

SECTION IV. Inspection of Dairy Farms and Plants ~~Bottling~~ Producing and Packaging Raw Milk and Raw Milk Products for Human Consumption.

A. Each dairy farm or plant manufacturing raw milk or raw milk products for human consumption shall be inspected by the Department prior to the issuance of a permit. Following the issuance of a permit, the Department shall inspect each dairy farm or plant at ~~least once every three (3) months. For the purposes of determining the inspection frequency for dairy farms producing raw milk for human consumption, the interval shall include the designated three (3) month period in addition to the remaining days of the month in which the inspection is due~~ a frequency determined by the risk level assigned to the product(s) being manufactured or distributed, or as otherwise deemed necessary by the Department. Inspections of dairy farms ~~shall~~will be made at milking time ~~as often as~~when possible.

B. ~~Should a violation of any requirement set forth in Section VII be 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 (3) days. This second inspection shall be used to determine compliance with the requirements of Section VII. Any violation of the same requirement of Section VII on such second inspection shall call for enforcement action pursuant to Section XI of this Regulation provided that when the Department finds that a critical processing element violation involving conditions whereby direct contamination of raw milk is occurring, the Department shall take immediate action to prevent further movement of such milk until such violations of critical processing element(s) have been corrected.~~ The Department shall conduct inspections and investigations as are necessary for the enforcement of this Regulation.

C. ~~One copy of the inspection report shall be handed producer, 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.~~ The inspector will notify the owner or other responsible person of the intent to inspect upon arrival at the premises.

D. ~~The Department shall also make such other inspections and investigations as are necessary for the enforcement of this Regulation.~~ 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.

E. ~~Inspection Notification - The inspector should advise the owner or other responsible person of the intent to inspect upon arrival at the premises.~~ Every raw milk producer shall, upon request of a Department representative, permit the 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 raw milk or raw milk product purchased and sold, and a list of all sources of ingredients, records of inspections, records of tests, and cooling time and temperature records.

F. ~~Every permit holder shall, upon request of the Department, allow access of officially designated persons to all parts of the permitted establishment or facilities to determine compliance with the provisions of this Regulation.~~ Should a violation of any requirement set forth in Section VII or Section VIII be 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 (3) calendar days. Any violation of a requirement of Section VII or Section VIII may result in enforcement action pursuant to Section XII of this Regulation. When the Department at any time finds that a critical processing element violation involving conditions whereby direct contamination of raw milk or raw milk products is occurring, the Department shall take immediate action to prevent transfer from the vessel or location of such raw milk or raw milk products until such violations of critical processing element(s) have been corrected.

G. It shall be unlawful for any person who, in an official capacity, under the provisions of this Regulation obtains any information of disposition of milk, or results of inspections or tests thereof to use such information to his/her own advantage or to reveal it to any unauthorized person.

SECTION ~~VI~~V. The Examination of Raw Milk and Raw Milk Products for Human Consumption.

A. Samples of raw milk or raw milk products for human consumption may be taken for ~~scientific examination~~analysis for public health purposes, at any reasonable time or place, and examined ~~bacteriologically or~~ for any other public health reason by ~~agents of~~ the Department.

B. Samples of raw milk and raw milk products for human consumption shall be collected and tested prior to a permit being issued. No permit shall be issued until the milk and milk products ~~meets~~meet the requirements of Section VII~~.A~~ and Section VIII.

C. The producer shall provide to the Department satisfactory pathogenic testing results prior to:

1. receiving a permit and beginning production and/or distribution; or

2. reinstatement of a permit that has been suspended because of positive results of testing for pathogenic organisms in association with a suspected outbreak of disease. In testing associated with a suspected outbreak of disease, the Department shall provide up to two (2) tests at no cost to the producer; pathogen testing required beyond these two (2) tests shall be the responsibility of the producer.

D. ~~During any consecutive six (6) months, at least four (4) samples of raw milk for human consumption shall be collected from each producer in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Department or shall be taken from each producer under the direction of the Department and delivered in accordance with this section.~~Samples of raw milk and raw milk products shall be collected by the producer or the Department, as directed, at a frequency that is deemed appropriate by the Department based on the level of risk of the product. The Department will require sampling for bacterial counts, somatic cell counts, coliform, cooling temperatures, drugs, pesticide residue, and/or pathogenic organisms as deemed appropriate by the Department. Sampling will be conducted in accordance with Department standard operating procedures for sampling of raw milk and raw milk products.

~~E. Required bacterial counts, somatic cell counts, and cooling temperature checks shall be performed on raw milk for human consumption. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.~~

~~F. When multiple samples of the same milk are collected from the same producer from multiple tanks on the same day, the laboratory results shall be averaged arithmetically by the Department and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.~~

~~G~~E. Whenever two (2) of the last four (4) consecutive bacterial counts, somatic cell counts, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the raw milk or raw milk products as defined in this Regulation, 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 (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one

(21) calendar days of the sending of such notice, but not before the lapse of three (3) calendar days. ~~Immediate suspension of permit shall be implemented~~The Department shall suspend the permit in accordance with Section XII whenever the standard is violated by three (3) of the last five (5) bacterial counts, coliform determinations, cooling temperatures, or somatic cell counts.

~~H. 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 milk 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.~~

~~I~~F. When sampling for pathogenic organisms is conducted in association with a suspected outbreak of disease, and the samples test positive for pathogenic organisms, such positive finding of pathogenic organisms shall be considered an imminent health hazard, and the product involved shall be disposed of and not be offered for sale. ~~the~~The Department shall immediately suspend the permit. The permit shall remain suspended until a representative sample containing a minimum of two (2) consecutive milkings are found to be free of pathogenic organisms.

~~J~~G. 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 latest edition of Standard Methods for the Examination of Dairy Products (SMEDP) of the American Public Health Association, and the latest edition of Official Methods of Analysis (OMA) of the Association of Official Agricultural Chemists (AOAC) International. Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance with the Evaluation of Milk Laboratories.

~~K~~H. All violations of bacteria, coliform, somatic cell counts, and cooling temperature standards shall be followed ~~promptly~~ by inspection, if needed, to determine and correct the cause.

~~L. Laboratory Techniques - Procedures for the collection and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with FDA 2400 Series forms, SMEDP and OMA.~~

~~1. The procedures shall be those specified therein for:~~

~~a. Standard plate count at 32°C (Agar or Petrifilm Method).~~

~~b. Alternate methods, including Plate Loop Count and the Bacto Scan FC and the Spiral Plate Count Method for viable counts for raw milk.~~

~~c. Coliform test with solid media or Petrifilm method at 32°C, and the Petrifilm High Sensitivity Coliform Count Method for all milk.~~

~~d. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk shall be used for each drug of concern. Regulatory action shall be taken on all confirmed positive results. A result shall be considered positive if it has been obtained by using a method that has been evaluated and deemed acceptable by FDA at levels established in memoranda transmitted periodically by FDA.~~

~~e. Screening and confirmatory methods for the detection of abnormal milk: The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.~~

~~(1) Milk (Non-Goat): Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting.~~

~~(2) Goat Milk: In addition to the above mentioned tests, the California Mastitis Test may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,000,000/mL. Laboratories using the Wisconsin Mastitis Test or California Mastitis Test for goat milk shall confirm samples of herd milk that exceeds 18mm, or a value of one (1), respectively. Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting. Pyronine-Y-Methyl green stain or "New York modification" shall be used in the confirmatory test for Direct Microscopic Somatic Cell Counts in goat milk.~~

~~f. Any other tests that have been approved by the Food and Drug Administration or the Centers for Disease Control and Prevention to be equally accurate, precise, and practical.~~

~~g. All standards used in the development and use of drug residue detection methods designed for Grade "A" PMO monitoring programs will be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method shall define the standard to be used.~~

~~M. Sampling Procedures - SMEDP guidance for sampling of milk shall be used:~~

~~1. When bacterial counts and temperature determinations are made of several samples of the same milk collected from the same producer on the same day, these values are averaged arithmetically, and the results recorded as the count or temperature determinations of the milk for that day. All counts and temperatures should be recorded on a milk ledger form for dairy farms as soon as reported by the laboratory.~~

~~2. A computer or other information retrieval system may be used.~~

~~N. Sampling Raw Milk - When samples of raw milk are taken, they shall be randomly drawn following adequate agitation. Sampling procedures shall not contaminate the sample of remaining milk, temperature when collected, and date and hour collected. The sample shall be immediately placed under refrigeration. Samples shall not be submerged in a coolant or handled in any manner which may cause contamination. All samples shall be maintained at 40°F (4°C) or below until analyzed. At no time shall the period of time between collection and analysis exceed forty eight (48) hours. Samples shall be collected by personnel who have been certified as sample collectors by Certified State Milk Sanitation Rating Officers.~~

SECTION VI. Labeling.

A. All bottles, containers, and packages enclosing raw milk or raw milk products for human consumption shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act (NLEA) of 1990 and regulations developed thereunder, and the Code of Federal Regulations, and shall comply with the applicable requirements of this section.

B. No person shall use any misleading marks, words, or endorsements upon the label. The Department may permit the use of registered trade designs or similar terms on the bottle cap or label when, in its opinion, they are not misleading and are not used to obscure the labeling required by the Regulation.

C. All bottles, containers, and packages enclosing raw milk or raw milk products for human consumption shall be conspicuously marked with:

1. The word "Raw" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.

2. The identity of the farm where packaged. This identity shall include the name and the Department Permit Number.

3. The following consumer advisory, in print no smaller than six (6) point font, shall be included on the package: "This is a raw milk product that is not pasteurized. Consuming raw milk products may increase your risk of foodborne illness."

4. The common name of the hooved mammal producing the milk shall precede the name of the milk or raw milk product when the product is made from other than cattle's milk. As an example, "Goat," "Sheep," "Water Buffalo," or "Other Hooved Mammal" milk, respectively.

D. Raw milk that has had cream separated from it must also be labeled as per Section VIII.B.3.

E. The term Grade "A" Raw may only be used with the designation of SC to read "SC Grade 'A' Raw". Other grade designations may not be used.

F. Descriptive labeling terms such as "wholesome" or "healthy" must not be used. The label must not be false or misleading. The use of the term "cultured" is allowed and optional for buttermilk and kefir.

G. A permit holder's label and Department permit number are not transferable and may only be used by that permit holder.

SECTION VII. Standards for Raw Milk and Raw Milk Products for Human Consumption.

A. General

1. All ~~Grade "A"~~ raw milk and raw milk products for human consumption shall be produced to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of this section.

2. No process or manipulation other than appropriate refrigeration shall be applied to raw milk or raw milk products for the purpose of removing or deactivating microorganisms.

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards		
SC GRADE "A" RAW MILK AND RAW MILK PRODUCTS FOR HUMAN-CONSUMPTION	Temperature	Raw milk: 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 milking, provided, that the blend temperature after the first and subsequent milkings does not exceed 10°C (50°F).

		Raw milk and raw milk products: All finished, processed, and packaged raw milk and raw milk products shall be maintained at 7°C (45° F) or less after processing, during storage, and during transportation. Production of buttermilk shall also meet the requirements of Section VIII.A.3.
	Bacterial Limits	Individual producer raw milk and raw milk products not to exceed 10,000 per mL
	Drugs	No positive results on drug residue detection methods ~~as referenced in Section VI - Laboratory Techniques.~~
	Somatic Cell Count*	Individual producer raw milk not to exceed 500,000 per mL.
	Coliform	Not to exceed 10 per gram.
	Pathogenic Organisms: **Escherichia Coli	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms
	**0157:H7	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms
	**Salmonella	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms
	**Listeria Monocytogenes	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms
	**Campylobacter	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms

*Goat Milk 1,000,000 per mL: when greater than 1,000,000, additional confirmatory or screening tests will be used.
**Pathogenic testing required before permitting and in association with a foodborne disease outbreak. See Section V.C.1, V.C.2, and V.F.

B. Sanitation Requirements for SC Grade "A" Raw Milk and Raw Milk Products ~~F~~for Human Consumption.

1. Milk with Abnormalities

a. Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment and the milk shall be discarded as the Department may direct.

b. Lactating animals that have been treated with, or have ~~consummed~~consumed, chemical, medicinal, or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Department, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Department may direct. ~~(For applicability to automatic milking installations (AMI's), refer to Appendix Q of the PMO.)~~

c. ~~Milk~~Raw milk or raw milk products from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, shall not be offered for sale for such period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

d. ~~Milk~~Raw milk or raw milk products from lactating animals treated with or exposed to insecticides not approved for use on dairy animals by the United States Environmental Protection Agency shall not be offered for sale.

e. The Department may require additional tests for the detection of milk with abnormalities as it deems necessary.

f. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, shall be handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

g. Lactating animals secreting milk with abnormalities shall be milked last or in separate equipment which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk shall be maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animals.

h. Equipment, utensils, and containers used for the handling of milk with abnormalities shall not be used for the handling of raw milk or raw milk products to be offered for sale, unless they are first cleaned and effectively sanitized.

i. Processed animal waste derivatives used as a feed ingredient for any portion of the total ration of the lactating dairy animal shall:

(1) ~~b~~Be properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and

(2) ~~n~~Not contain levels of deleterious substances, harmful pathogenic organisms, or other toxic substances which are secreted in the milk at any level that may be ~~deleterious~~harmful to human health.

j. Unprocessed poultry litter and unprocessed recycled animal body discharges shall not be fed to lactating dairy animals.

2. Milking Barn, or Parlor Construction

A milking barn or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations.

a. All floors must be constructed of concrete or equally impervious material~~; convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix C. III. of the PMO~~. Floors shall be easily cleaned and shall be graded to drain and maintained in good repair and free of excessive breaks or worn areas that may create pools.

b. Walls and ceilings shall be smooth, painted, or finished in an approved manner, and ~~are~~be in good repair. Ceilings shall be dust-tight; approved materials include wood, tile, smooth-surfaced concrete, cement plaster, brick, or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident. Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable, or parlor. If a hay opening is provided from the loft into the milking portion of the barn, such opening shall be provided with a dust-tight door which shall be kept closed during milking operations.

c. Separate stalls or pens for horses, calves, and bulls shall be provided. Such portions of the barn that are not separated by tight partitions shall comply with all requirements of this item.

d. Natural and/or artificial light well distributed for day and/or night milking must be provided to ~~insure~~ensure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten (10) foot-candles (110 lux) of light in all working areas shall be provided.

e. Sufficient air space and air circulation to prevent condensation and excessive odors ~~will~~must be provided.

f. There ~~will~~must be no overcrowding ~~which will be evidenced~~ by the presence of calves, cows, or other barnyard animals in walk~~s~~ or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn. ~~It is recommended that pit areas in parlors should be at least six (6) feet in width from overhang when cows are milked on two (2) sides, and six (6) feet working areas when single row of stalls. Ceiling height shall be at least seven (7) feet in areas where cows stand;~~

g. There must be dust-tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed. A dust-tight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored. When conditions warrant, the Department may approve a barn without four (4) walls extending from floor to roof, or a shed-type barn provided the requirement of Section VII.B.3~~.~~, which ~~prohibiting~~prohibits animals and fowl from entering the barn, is satisfied. Lactating animal-housing areas (stables without stanchions, such as loose housing stables, pen stables, resting barns, free stall barns, holding barns, loafing sheds, and wandering sheds) may be of shed-type construction, provided no milking is conducted therein. (These structures are classified as part of the cowyard under Section VII.B.4.)

h. The Department may grant a variance or waiver from one or more of the requirements of paragraphs VII.B.2.a through VII.B.2.g when, in the opinion of the Department, a health hazard or nuisance will not result from the variance or waiver.

3. Milking Barn, Stable, or Parlor Cleanliness

a. The interior of the milking barn, stable, or parlor shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be free of filth and/or litter and shall be clean. Outside surfaces of pipeline systems located in the milking barn, stable, or parlor must be kept reasonably clean.

b. Gutter cleaners must be kept reasonably clean.

c. Swine and fowl shall be kept out of the milking barn.

~~d. All pens, calf stalls, and bull pens, if not separated from the milking barn, stable, or parlor, must be kept clean.~~

~~e~~d. Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor (as in covered, dust-tight boxes or bins). Open feed dollies or carts may be used for distributing the feed, but not storing food, in the milking area.

~~f. Milk stools, surcingles, and antikickers shall be kept clean and stored above the floor in a clean place in the milking barn, stable, parlor or milkhouse, when not in use.~~

~~g~~e. Food mangers shall be kept clean so as not to attract flies; leftover feed in feed mangers must appear fresh and not be wet or soggy.

4. Cowyard

a. The cowyard, which is interpreted to be the enclosed or unenclosed area approximately adjacent to the milking barn in which the lactating animals may congregate, including animal-housing areas and feed lots, shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes.

b. Wastes from the barn, ~~or milkhouse~~milkroom, or processing room shall not be allowed to pool in the cowyard. Depressions and soggy areas shall be filled, and lactating animal lanes kept reasonably dry. Cowyards which are muddy due to recent rains should not be considered as violating this item.

c. Manure, soiled bedding, and waste feed shall not be stored or permitted to accumulate in such a manner as to permit the soiling of lactating animals' udders and flanks. Animal-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered part of the cowyard. Manure packs shall be solid to the footing of the animal.

d. In loafing or lactating animal housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating animal's udder and flanks.

~~e. Cooling ponds shall be allowed provided they are constructed and maintained in a manner that does not result in the visible soiling of flanks, udders, bellies, and tails of lactating animals exiting the pond.~~

~~f~~e. Waste feed shall not be allowed to accumulate.

~~g~~f. Swine shall be kept out of the cowyard.

~~h~~g. Cowyards shall be kept reasonably free of animal droppings. Animal droppings shall not be allowed to accumulate in piles that are accessible to the animals.

5. ~~Milkhouse~~Milkroom or Processing Room—Construction and Facilities

a. A separate ~~milkhouse~~milkroom and/or processing room of sufficient size shall be provided, in which the cooling, handling, further processing, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted, except as provided for in Section VII.B.12 of this Regulation.

b. ~~The milkhouse~~Every milkroom and processing room shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Floors shall be sloped to drains so that there are no pools of standing water. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

c. The joints between floors and walls shall be watertight.

d. The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner. Surfaces and joints shall be tight and smooth. Acceptable materials include sheet metal, tile, cement block, brick, concrete, cement plaster, or similar materials of light color. Surfaces up to splash height shall be non-absorbent and easily cleanable.

e. ~~The milkhouse~~Every milkroom and processing room shall have adequate natural and/or artificial light and be well ventilated. A minimum of twenty (20) foot-candles (220 lux) of light shall be provided at all working areas from natural and/or artificial light for ~~milkhouse~~milkroom and processing room operations.

f. The ~~milkhouse~~milkroom and processing room shall be used for no other purpose than ~~milkhouse~~milkroom and processing room operations; there shall be no direct opening into any barn, stable, parlor or into a room used for domestic purposes. A direct opening between the ~~milkhouse~~milkroom or processing room and milking barn, stable or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting is provided and opens outward from the milk room. A vestibule, if used, must comply with the applicable ~~milkhouse~~milkroom and processing room construction requirements. Screened vents in the wall between the ~~milkhouse~~milkroom or processing room and a breezeway, which separates the ~~milkhouse~~milkroom or processing room from the milking parlor, are permitted, provided animals are not housed within the milking facility.

g. Water under pressure shall be piped into the ~~milkhouse~~milkroom and/or processing room.

h. ~~The milkhouse~~Every milkroom and processing room shall be adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.

i. Vents, if installed, and lighting fixtures shall be located to preclude the contamination of bulk milk tanks or clean utensil storage area.

j. The ~~milkhouse~~milkroom and/or processing room shall be equipped with a wash-and-rinse vat having at least two (2) compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The cleaning-in-place vat for milk pipelines and milk machines may be accepted as one (1) part of the two (2)-compartment vat; provided that the cleaning-in-place station rack in or on the vat and milking machine inflations and appurtenances are completely removed from the vat during the washing, rinsing, and/or sanitizing of other utensils and equipment. Where mechanical cleaning/recirculated systems eliminate the need for handwashing of equipment, the presence of the second wash vat compartment may be optional if so determined by the Department on an individual farm basis.

k. Each ~~milkhouse~~milkroom and/or processing room shall be provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils.

6. ~~Milkhouse or Room~~Milkroom and Processing Room – Cleanliness

a. The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils, and equipment, and other ~~milkhouse~~milkroom or processing room equipment shall be kept clean. Vestibules, if provided, shall be kept clean.

b. Only articles directly related to ~~milkhouse~~milkroom or processing room activities shall be permitted in the ~~milkhouse~~milkroom or processing room.

c. The ~~milkhouse~~milkroom and processing room shall be kept free of trash, animals, and fowl.

d. Incidental articles such as desks, refrigerators, and storage cabinets may be in the ~~milkhouse~~milkroom or processing room provided they are kept clean, ample space is available to conduct the normal operations in the ~~milkhouse~~milkroom or processing room, and they will not cause contamination of the milk.

7. Toilet

a. Every dairy farm shall be provided with one (1) or more toilets, conveniently located and properly constructed, operated, maintained and utilized in a sanitary manner. There shall be at least one (1) flush toilet connected to a public sewer system or to an individual sewage-disposal system, or if occupied for less than two (2) hours per day, a portable chemical toilet may be used~~, earth pit privy or other type of privy~~. Such ~~sewerage~~sewage systems shall be constructed and operated in accordance with applicable Department regulations and statutes.

b. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply. ~~Vents of earth pits shall be screened.~~

~~c. No privy shall open directly into the milkhouse.~~

~~d~~c. The toilet room, including all fixtures and facilities, shall be kept clean and free of insects and odors.

~~e~~d. Where flush toilets are used, doors to toilet rooms shall be tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of insects.

8. Water Supply

a. Water for ~~milkhouse~~milkroom or processing room and milking operations shall be from an approved supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

b. No cross-connection shall exist between a safe water supply and any unsafe or questionable water supply, or any other source of pollution.

c. There shall be no submerged inlets through which a safe water supply may be contaminated.

d. The well or other source of water shall be located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy, or other source of pollution can reach such water supply.

e. New individual water supplies and water supply systems that have been repaired or otherwise become contaminated shall be thoroughly disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

f. All containers and tanks used in the transportation of water shall be sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or

groundwater storage at the dairy farm, a suitable pump, hose, and fittings shall be provided. When the pump, hose, and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material provided with a dust and rainproof cover, ~~and provided with~~as well as with an approved-type vent and roof hatch. All new reservoirs, or reservoirs which have been cleaned, shall be disinfected prior to placing them into service.

g. Samples for bacteriological examination shall be taken upon the initial approval of the physical structure based upon the requirements of this Regulation, when any repair or alteration of the water supply system has been made, and at least every ~~three (3)~~ years~~, provided that:~~.

~~(1) water supplies with buried well casing seals installed prior to the adoption of this section shall be tested at intervals no greater than six (6) months apart. Whenever such samples indicate either the presence of bacteria of the coliform group, or whenever the well casing, pump or seal needs replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this section.~~

~~(2) when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four (4) times in separate months during any consecutive six (6) months.~~

h. Bacteriological examinations shall be conducted in a laboratory acceptable to the Department.

~~i. To determine if water samples have been taken at the frequency established in this section, the interval shall include the designated period plus the remaining days of the month in which the sample is due.~~

~~j~~i. Current records of water test results shall be retained on file with the Department or as the Department directs.

9. Utensils and Equipment – Construction

a. All multiuse containers, equipment, and utensils that are exposed to raw milk or raw milk products, or from which liquids may drip, drain or be drawn into raw milk or raw milk products, and used in the handling, storage, or transportation of milk shall be made of smooth, non-absorbent, corrosion-resistant, nontoxic materials, and shall be constructed to be easily cleaned. Acceptable materials include:

(1) ~~s~~Stainless steel of the AISI (American Iron and Steel Institute) 300 series, or equally corrosion-resistant, nontoxic metal;

(2) ~~h~~Heat-resistant glass; or

(3) ~~p~~Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion~~,~~ under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent, and 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.

b. All containers, utensils, and equipment shall be in good repair and shall be free of breaks, corrosion, pits, cracks, or inclusions.

c. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Seamless hooded pails having an opening not exceeding one-third the area of that of an open pail of the same size shall be used for hand milking and hand stripping.

d. Strainers, if used, shall be constructed of perforated metal design, or single-service strainer media should be utilized. Multiple-use woven material shall not be used for straining milk.

e. All single-service articles shall be manufactured, packaged, transported, stored, and handled in a sanitary manner and shall comply with the applicable requirements of Section ~~VIII~~IX. Articles intended for single-service use shall not be reused.

f. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of Section VII.B.9.a, g, and h.

g. Mechanically cleaned milk pipelines and return-solution lines shall be self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in Section VII.B.9.a.(3), and shall be of such design, finish, and application as to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks, and inclusions.

h. Mechanically cleaned milk pipelines and return solution lines installed after the effective date of this Regulation shall have welded ferrule/flange fittings; rolled fittings shall not be used.

i. Detailed plans for cleaned-in-place pipeline systems shall be submitted to the Department for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Department.

j. All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces shall be constructed to be easily cleaned and inspected. Pipelines, milking equipment, and appurtenances that require a ~~screw driver~~screwdriver or special tool shall be considered easily accessible for inspection, provided the necessary tools are available at the ~~milkhouse~~milkroom or processing room. Milking systems shall not have components incorporated in the return solution lines~~,~~ that by design do not comply with the criteria for product-contact surfaces, such as:

(1) ~~b~~Ball type plastic valves;

(2) ~~p~~Plastic tees with barbed ridges to better grip the plastic or rubber hoses; and

(3) PVC water type piping.

k. Milk cans shall have umbrella-type lids.

l. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of this Regulation.

m. During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill and top fill bulk milk storage tanks, when needed for functional purposes. Such hoses shall be drainable, be as short as practical, have sanitary fittings, and be supported to maintain uniform slope and alignment. The end fittings of such hoses shall be permanently attached in such a manner that will assure a

crevice-free joint between the hose and the fitting and can be cleaned by mechanical means. The hoses shall be included as part of a mechanical cleaning system.

n. Transparent flexible plastic tubing (up to 150 feet in length) used in connection with milk transfer stations shall be considered acceptable if it meets the "3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20" and if it remains sufficiently clear that the interior surfaces can be properly inspected. Short lengths of flexible plastic tubing (eight [8] feet or less) may be inspected for cleanliness by sight or by use of a "rod." ~~:~~ The transparency or opacity of such tubing under this condition is not a factor in determining cleanliness.
~~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, Food and Drug Administration, Public Health Service, Center for Food Safety and Applied Nutrition, Department of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Regulation.~~

o. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it shall be free of oil, dust, rust, excessive moisture, extraneous materials, and odor.

10. Utensils and Equipment—Cleaning

a. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of raw milk and raw milk products shall be cleaned after each milking or once every twenty-four (24) hours for continuous operations.

b. There shall be a separate wash manifold for all mechanically cleaned milk pipelines in all new or extensively remodeled facilities.

11. Utensils and Equipment – Sanitization

a. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of raw milk and raw milk products shall be sanitized before each usage.

b. Sanitization shall be achieved by use of the following methods:

(1) Complete immersion in hot water at a temperature of at least 77°C (170°F), for at least five (5) minutes, or exposure to a flow of hot water at a temperature of at least 77°C (170°F), as determined by the use of a suitable accurate thermometer (at the outlet) for at least five (5) minutes;

(2) Complete immersion for at least one (1) minute in or exposure for at least one (1) minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces must be wetted by the sanitizing solution, and piping so treated must be filled. Sanitizing sprays may be used. Chemical solutions, once used, shall not be reused for sanitizing but may be reused for other purposes; or

(3) By any method which has been demonstrated to be equally effective and approved by the FDA, EPA, or the Department.

12. Utensils and Equipment – Storage

a. All containers, utensils, and equipment used in the handling, storage, or transportation of raw milk and raw milk products, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use, except that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers, ~~and~~ milk pumps, and AMI milking equipment which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed, and operated to protect the product and solution-contact surfaces from contamination at all times.

b. Strainer pads, parchment papers, gaskets, and similar single-service articles shall be stored in a suitable container or cabinet and protected against contamination.

13. Utensils and Equipment—Handling

After sanitization, all containers, utensils, and equipment shall be handled in a manner that prevents contamination of any product-contact surface.

a. Sanitized product-contact surfaces, including farm cooling holding tank openings and outlets, shall be protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation, and other sources of contamination.

b. Any sanitized product-contact surface which has been otherwise exposed to contamination shall be cleaned and sanitized before being used.

14. Milking—Flanks, Udders, and Teats

a. Milking shall be done in the milking barn or parlor.

b. The flanks, udders, bellies, and tails of all milking cows shall be free from ~~visable~~visible dirt. All brushing shall be completed prior to milking.

c. The udders and teats shall be cleaned and treated with a sanitizing solution just prior to the time of milking, and shall be relatively dry before milking. Sanitizing solutions shall be used in accordance with manufacturer specifications and recommendations.

d. Wet hand milking is prohibited.

e. Flanks, bellies, tails, and udders shall be clipped as often as necessary to facilitate cleaning of these areas.

15. Drug and Chemical Control

a. Cleaners and Sanitizers

(1) Cleaners and sanitizers shall be stored in dedicated end-use containers which properly identify the contents.

(2) Bulk cleaners and sanitizers that are transferred from the manufacturer's or distributor's container shall be stored only in an end-use container that is properly labeled with the container's contents.

(3) The manufacturer's or distributor's label for each cleaner and sanitizer, including the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor, shall be maintained on the premises and be readily accessible for reference or inspection.

b. Drugs

(1) Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for over-the-counter (OTC) drugs or veterinary practitioner dispensing the product for prescription and extra label use drugs. Drug labels shall also include:

(a) ~~d~~Directions for use and prescribed withholding times;

(b) ~~c~~Cautionary statements, if needed; and

(c) ~~a~~Active ingredient(s) in the drug product.

(2) Drugs dispensed by a pharmacy on the order of a veterinarian shall have labeling that includes the name of the prescribing veterinarian and the name and address of the dispensing pharmacy; the address of the prescribing veterinarian may be included on the labeling.

(3) Drugs intended for treatment of non-lactating dairy animals shall be segregated from those drugs used for lactating animals in separate shelves in cabinets, refrigerators, or other storage facilities.

(4) Unapproved drugs shall not be used and shall not be stored in the ~~milkhouse~~milkroom, processing room, milking barn, stable, or parlor.

(5) Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats, and hand sinks are not subject to contamination by the drugs.

(6) Equipment used to administer drugs shall not be cleaned in the wash vats.

~~NOTE:~~(7) Topical antiseptics and wound dressings, unless intended for direct injection into the teat, vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements, except when it is determined that they are stored in such a manner that they may contaminate the raw milk or raw milk product-contact surfaces of containers, utensils, or equipment.

16. Milking—Transfer and Protection of Milk

a. Each pail or container of milk shall be taken immediately from the milking barn or parlor to the ~~milkhouse~~milkroom or processing room. No milk shall be strained, poured, transferred, or stored outside the ~~milkhouse~~milkroom or processing room.

b. The milk receiving receptacle shall be raised above the floor.

17. Personnel

a. Adequate handwashing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent, and individual sanitary towels, or other approved hand

drying devices, convenient to the ~~milkhouse~~milkroom, processing room, milking barn, stable, parlor and flush toilet, and shall be used for no other purpose. Utensil wash and rinse vats shall not be considered as handwashing facilities.

b. Hands shall be washed clean and dried with an individual sanitary towel or other approved hand drying device immediately before milking, before performing any ~~milkhouse~~milkroom or processing room function, and immediately after the interruption of any of these activities. Milkers shall wear clean outer garments while milking or handling raw milk, raw milk products, milk containers, utensils, or equipment.

c. No 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 shall work at any dairy farm in any capacity that brings them into contact with the production, handling, storage, or transportation of raw milk, raw milk products, containers, equipment, and/or utensils. ~~Any producer or distributor of milk 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 immediately.~~

d. When reasonable cause exists to suspect the possibility of transmission of infection or disease from any person ~~concerned~~associated with the handling of raw milk or raw milk products, the Department may:

(1) ~~o~~Order the immediate exclusion of that person from raw milk handling or handling of raw milk products;

(2) ~~o~~Order the immediate exclusion of the raw milk or raw milk products ~~supply~~ concerned from distribution and consumption;

(3) ~~o~~Order adequate medical and bacteriological examination of the person to determine if ~~the~~an infection or disease is present; or

(4) ~~o~~Order any combination of the previous measures.

18. Cooling

a. Raw milk shall be 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, and shall be maintained at that temperature, including during packaging and transportation; except that, the blend temperature after the first milking and subsequent milking shall not exceed 10°C (50°F).

b. All finished, processed, and packaged raw milk and raw milk products shall be maintained at 7°C (45° F) or less after processing, during storage, and during transportation.

~~b~~c. Recirculated cold water that is used in plate or tubular coolers or heat exchangers shall be from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards set by the Department.

~~c. All farm bulk milk tanks manufactured after January 1, 2000, shall be equipped with an approved temperature-recording device.~~

~~(1) The recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap.~~

~~(2) The recording device shall be verified every six (6) months and documented in a manner acceptable to the Department using an accurate (+/- 1°C (2°F)) thermometer that has been calibrated by a traceable standard thermometer, within the past six (6) months, with the results and date recorded and the thermometer being properly identified, or by using a traceable standard thermometer that has been calibrated within the last year.~~

~~(3) Recording thermometer charts shall be maintained on the premises for a period of a minimum of six (6) months and available to the Department.~~

~~(4) The recording thermometer should be installed in an area convenient to the milk storage tank and acceptable to the Department.~~

~~(5) The recording thermometer sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than ten (10) percent of its calibrated capacity.~~

~~(6) The recording thermometer shall comply with the current technical specifications for tank recording thermometers.~~

~~(7) A recording thermometer and/or any other device that meets the intent of this Regulation and technical specifications, and is acceptable to the Department, can be used to monitor/record the bulk tank temperature.~~

~~(8) The recording thermometer charts shall properly identify the producer, date, and signature of the person removing the chart.~~

19. Vehicles.

Vehicles used to transport raw milk and raw milk products shall be constructed and operated to protect their contents from sun, freezing, and contamination. Such vehicles shall be kept clean, inside and out; ~~and~~ no substance capable of contaminating raw milk or raw milk products shall be transported with raw milk or raw milk products.

20. Insect and Rodent Control.

a. Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents, and by chemicals used to control such vermin.

b. Milkrooms and processing rooms shall be free of insects and rodents.

c. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents.

d. Feed shall be stored in such a manner that it will not attract birds, rodents, or insects.

e. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds, and free-stall housing shall be properly bedded and managed to prevent fly breeding.

f. Milkrooms and processing rooms shall be effectively screened or otherwise protected against the entrance of vermin, including hose ports and floor drains through walls.

g. Outer ~~milkhouse~~milkroom and processing rooms doors shall be tight and self-closing. Screen doors shall open outward.

h. Only pesticides approved for use by the Department and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

i. Pesticides shall be used only in accordance with manufacturer's directions.

SECTION VIII. Standards for Further Processing of Raw Milk Products.

A. Buttermilk

1. All equipment used for the production and processing of buttermilk must be smooth, non-absorbent, and easily cleanable.

2. All ingredients must come from an approved source.

3. The pH of the buttermilk must be maintained at 4.6 or below following production and at the time of packaging, or the product must be maintained at 7°C (45° F) or below. All finished, processed, and packaged buttermilk must meet the requirements of VII.B.18.b.

B.Cream

1. All equipment used for the production and processing of cream must be smooth, non-absorbent, and easily cleanable.

2. Cream must be removed from the raw milk vat by the use of a separator or other method approved by the Department. The hand skimming of cream is prohibited.

3. Raw milk that has had the cream removed shall be labeled as "Raw Milk with Cream Removed."

4. All finished, processed, and packaged cream must meet the requirements of VII.B.18.b.

C. Kefir

1. All equipment used for the production and processing of kefir must be smooth, non-absorbent, and easily cleanable.

2. All ingredients must come from an approved source.

3. The product may contain harmless edible stabilizers not to exceed six-tenths of 1 percent (0.6%). Kefir shall contain no more than 10 coliform bacteria per gram and shall be free of molds, yeasts, and other fungi, and other objectionable bacteria that may impair the quality of the product.

4. Conformance with the requirements of I.A.14 and VIII.C.3 shall be demonstrated by a product assessment conducted by a third-party process authority and provided to the Department by the raw milk processor if requested by the Department.

5. All finished, processed, and packaged kefir must meet the requirements of VII.B.18.b.

SECTION ~~VIII~~ IX. Bottling, Packaging, Container Filling, and Container Closure/Sealing.

A. Bottling, Packaging, and Container Filling.

1. Bottling, packaging, and container filling of raw milk and raw milk products shall be done at the place of production in a sanitary manner by approved mechanical equipment. Bottling, packaging, and container filling of raw milk or raw milk products may be conducted in the ~~milkhouse~~milkroom and processing rooms or room.

2. Bottling or packaging machine supply tanks and bowls shall have covers which are smooth and easily cleanable and shall be constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

3. A drip deflector shall be installed on each filler valve. The drip deflector shall be designed and adjusted to divert condensation away from the open container.

4. All containers, seals, and caps shall be from an approved Interstate Milk Shippers listed facility.

5. All containers, seals, and caps shall be handled in a sanitary manner and protected against undue exposure during the operation.

6. When any lubricant is applied to the filler equipment or other milk contact surfaces, the lubricant shall be food grade and applied in a sanitary manner.

7. Containers shall be closed immediately after being filled.

B. Container Closure/Sealing.

1. All container caps, sealers, and closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination.

2. Only new containers, container caps, sealers, and closures shall be used. Reusable glass containers must be approved by the Department prior to use.

3. All container closure/sealing shall be done at the place of production in a sanitary manner by approved mechanical equipment.

4. Hand capping or sealing of containers is prohibited.

5. If suitable mechanical equipment for the capping or closing of specific container(s) of 12.8 liters (three [3] gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by the Department. Approval of such methods shall be obtained prior to beginning operation.

6. Bottles and packages which have been imperfectly capped, sealed, or closed shall have the contents emptied immediately into approved sanitary containers that are protected from contamination and maintained at 7°C (45°F) or less; when handled and stored properly, the contents may be repackaged in new containers at a later time.

7. All caps, seals, and closures shall be designed and applied so that the sealed container is tamper-evident (removal cannot be made without detection), and the pouring lip shall be protected to at least its largest diameter.

8. Caps, sealers, and closures shall not be left in the equipment at the end of an operating period. Caps, sealers, and closures remaining in the chute between the hopper and the capping device shall be discarded.

9. Loose caps, sealers, and closures may be returned to storage by enclosing them in a clean, protective wrap, plastic bag, or container approved by the Department.

SECTION ~~IX~~ X. Animal Health.

A. All raw milk and raw milk products for human consumption within ~~the State of~~ South Carolina shall be from healthy animals. ~~Milk~~ Raw milk and raw milk products from unhealthy animals shall not be offered for sale, barter, or be given away, or combined with other raw milk~~,~~ or raw milk products for human ~~consumption~~.

B. All animals producing raw milk or raw milk products for human consumption shall be ~~tested~~free of ~~for~~ brucellosis and tuberculosis ~~every twelve (12) months~~. Animals showing positive by lesions or a positive test shall be reported to the Department~~,~~ and shall also be reported to the State Veterinarian office in accordance with applicable law.~~:~~

~~1. Shall be separated, and kept separate, from the remainder of the herd;~~

~~2. A certificate, identifying each animal, signed by a licensed veterinarian and the director of the laboratory making the test, shall be filed with the Department;~~

~~3. Shall be retested by a licensed veterinarian at a frequency specified by the United States Department of Agriculture (USDA), and test results shall be filed with the Department; and~~

~~4. Disposition of diseased animals shall be conducted in accordance with guidelines published by the USDA and shall be reported to the Department.~~

C. For diseases other than brucellosis and tuberculosis, the Department shall require such physical, chemical, or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed veterinarian. Any diseased animal disclosed by such test(s) shall be disposed of as the Department directs.

D. Animals shipped into South Carolina for additions to herds shall have been tested for tuberculosis and brucellosis within thirty (30) calendar days prior to being brought into the state, except that this shall not apply, with regard to brucellosis, to those cattle that have been vaccinated for brucellosis and are under thirty (30) months of age.

E. Records supporting the tests required in this section shall be made available to the Department and be validated with the signature of a licensed veterinarian.

SECTION ~~X~~ XI. Recall.

Each producer and distributor of raw milk and raw milk products for human consumption 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 producer, distributor, 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 producer or distributor, 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 producer or distributor to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The producer or distributor shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION ~~XI~~ XII. Enforcement.

A. General.

This Regulation is issued under the authority of Sections 44-1-140(3) and 44-1-150, S.C. Code of Laws, 1976, as amended. It shall be enforced in accordance with interpretations and public health reasons approved by the Department.

B. Penalties.

Any person found to be in violation of this Regulation, in noncompliance 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.

~~B.~~C. Suspension of Permit.

~~1. The Department may, without warning, notice or hearing, suspend the permit of any producer or distributor of raw milk whenever, in the opinion of the Department, an imminent health hazard exists. An imminent health hazard includes, but is not limited to, violations of bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards, or the presence of pathogenic organisms. Upon such suspension of permit, all bottling and/or distribution activities shall immediately cease and remain ceased while the permit is suspended. The suspension of permit shall remain in effect until the imminent health hazard has been corrected to the satisfaction of the Department.~~

~~2.~~1. The Department may ~~otherwise~~ temporarily suspend a permit ~~for a violation of this Regulation when~~whenever:

a. ~~i~~It has reason to believe that a public health hazard exists;

b. ~~t~~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;

~~c.~~d. ~~t~~The permit holder has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit; or

~~d.~~e. ~~t~~The permit holder exhibits hostile behavior toward a representative of the Department during the performance of duty.

2. The Department may, without warning, notice, or hearing, immediately suspend the permit of any producer of raw milk or raw milk products whenever, in the opinion of the Department, an imminent health hazard exists. An imminent health hazard may include, but is not limited to, a willful refusal to permit authorized inspection, serious or repeated violations of bacterial, coliform, somatic cell, or cooling temperature standards, violation of drug residue test standards, or the presence of pathogenic organisms. Upon such suspension of the permit, all processing, bottling, and/or distribution activities shall immediately cease and remain ceased while the permit is suspended. The suspension of permit shall remain in effect until the imminent health hazard has been corrected to the satisfaction of the Department.

3. A suspension of permit shall remain in effect until any violation has been corrected to the satisfaction of the Department.

~~C.~~D. Revocation of Permit. ~~The Department may revoke a permit when:~~

~~1. the permit holder has repeated suspension(s); or~~

~~2. the permit holder physically threatens or intimidates a representative of the Department.~~
The Department may revoke a permit for serious or 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 representatives in the performance of its duties, including willful refusal to allow an authorized inspection/audit. Notwithstanding any other provisions of this Regulation, the permit may be revoked if any Department representative is threatened with bodily harm or physical interference in the performance of inspectional duties.

~~D.~~E. Reinstatement of Permit

1. Any producer whose permit has been suspended may ~~make~~submit a written application for the reinstatement of the permit. Any application for the reinstatement of a suspended permit must be in writing and must address all violations underlying the suspension and explain the steps taken to correct those violations.

2. Within ~~one week~~seven (7) business days of the receipt of such an application, the Department shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine ~~that the applicant's establishment is complying with the requirements~~whether the conditions cited in the notice of suspension no longer exist. When the findings justify, the permit shall be reinstated.

3. When the permit suspension has been due to a violation of any of the bacteriological, coliform, somatic cell, cooling temperature, or drug residue test standards, the Department may issue a temporary permit whenever resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section VII. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3)-week period, and the Department shall reinstate the permit upon compliance with the appropriate standards as determined in accordance with Section ~~VI~~V of this Regulation.

4. When a permit has been revoked, the holder of the revoked permit may ~~make~~submit a written application for a new permit; however, the Department may deny a new permit based upon past history, including previous enforcement, suspension, or revocation history.

5. 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.

~~E. Other Enforcement Provisions~~

~~1. In addition to the authority to suspend and revoke permits, the Department may seek enforcement and issue civil penalties in accordance with SC Code Ann. Section 44-1-150, S.C. Code of Laws, 1976, as amended. The Department shall have the authority to assess and suspend civil penalties if the violations of this Regulation are corrected in a period of time established by the Department.~~

~~2. A Department decision involving the issuance, denial, renewal, modification, 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. Any person to whom an order or enforcement letter is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.~~

SECTION XIII. Delayed Implementation.

Existing raw milk or raw milk products permit holders in operation prior to the effective date of the below listed requirements of this Regulation may use labels that do not comply with those requirements (but which meet all labeling requirements previously in effect) until their existing supply of labels as of the effective date of the below requirements is exhausted or for no more than one (1) year from the effective date of these requirements, whichever is sooner:

1. As provided in Section VI.C.3, all labels shall include the following consumer advisory, in no smaller than six (6) point font: "Consuming raw milk products may increase your risk of foodborne illness."

2. As provided in Section VI.E, labels may only use the term Grade "A" Raw in conjunction with the designation of "SC," to read "SC Grade 'A' Raw". Other grade designations may not be used.

Raw milk or raw milk products permit holders permitted after the effective date of the requirements referenced in Section XIII.1 and XIII.2 above must comply with all of the labeling requirements of Section VI without any delayed implementation.

SECTION ~~XII~~ 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 this Regulation shall not be affected thereby.

61-34.1. Pasteurized Milk and Milk Products.

(Statutory Authority: S.C. Code Sections 44-1-140 and 44-1-150)

SECTION I. ~~APPLICABILITY OF THE GRADE "A" PASTEURIZED MILK ORDINANCE~~ Applicability of the Grade "A" Pasteurized Milk Ordinance, ~~2013~~2019 ~~REVISION~~ Revision

A. The following sections, appendices, and footnotes of the Grade "A" Pasteurized Milk Ordinance (PMO or Ordinance), ~~2013~~2019 Revision, apply in their entirety:

1. Section 4~~.~~, Labeling;

2. Section 6~~.~~, The Examination ~~Of~~of Milk ~~And/Or~~and/or Milk Products;

3. Section 7~~.~~, Standards ~~For~~for Grade "A" Milk ~~And/Or~~and/or Milk Products (including Items 1r through 19r, and 1p through 22p);

4. Section 8~~.~~, Animal Health;

5. Section 9~~.~~, Milk ~~And/Or~~and/or Milk Products Which May Be Sold;

6. Section 10~~.~~, Transferring; Delivery Containers; Cooling;

7. Section 11~~.~~, Milk ~~And/Or~~and/or Milk Products ~~From~~from Points Beyond ~~The~~the Limits ~~Of~~of Routine Inspection;

8. Section 12~~.~~, Plans ~~For~~for Construction ~~And~~and Reconstruction;

9. Section 13~~.~~, Personnel Health;

10. Section 14~~.~~, Procedures When Infection ~~Or~~or High Risk ~~Of~~of Infection Is Discovered;

11. Section 18~~.~~, Separability Clause;

12. Footnotes; and

13. Appendices A through S.

B. The following associated documents of the Grade "A" Pasteurized Milk Ordinance, ~~2013~~2019 Revision, apply in their entirety:

1. Procedures Governing the Cooperative State - Public Health Service, Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, ~~2013~~2019 Revision (Procedures);

2. Methods of Making Sanitation Ratings of Milk Shippers, ~~2013~~2019 Revision (Methods); and

3. Evaluation of Milk Laboratories, ~~2013~~2019 Revision.

C. The following provisions of the Grade "A" Pasteurized Milk Ordinance, ~~2013~~2019 Revision, apply with the additions, exceptions, and superseding amendments specified below:

1. Section 1~~.~~, Definitions applies with the following exceptions:

a. ~~The definition RR. Regulatory Agency applies with the following amendment:~~ Definition YY, Regulatory Agency, shall be stricken, and the term "Regulatory Agency," where used in the Pasteurized Milk Ordinance, 2019 Revision, shall be replaced with the term "Department." The Department shall mean the South Carolina Department of Health and Environmental Control or its authorized representative.

~~RR. **REGULATORY AGENCY:** The Regulatory Agency shall mean the State of South Carolina's Department of Health and Environmental Control ("the Department") or their authorized~~

~~representative. The term, "Regulatory Agency", whenever it appears in the *Ordinance* shall mean the appropriate agency, including a Third Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), having jurisdiction and control over the matters embraced within this *Ordinance*.~~

b. Ordinance, as used in the Pasteurized Milk Ordinance, ~~2013~~2019 Revision, shall mean the provisions and appendices of the Pasteurized Milk Ordinance, ~~2013~~2019 Revision, as adopted by the South Carolina Department of Health and Environmental Control ("the Department").

c. "… of …", as used in the Pasteurized Milk Ordinance, 2019 Revision, shall mean the state of South Carolina.

d. Cross-references to "Section 3. of this *Ordinance*" appearing in Section 5, Section 6, and Appendix N shall mean Section C.3 of this Regulation together with applicable portions of Section 3 of the Ordinance.

2. Section 2~~.~~, Adulterated ~~Or~~or Misbranded Milk ~~And/Or~~and/or Milk Products, applies ~~with the following exceptions~~in its entirety with the following additions:

a. The following applies in addition to Section 2:

Milk and milk products shall be examined by the ~~Regulatory Agency~~Department as often as may be necessary to determine freedom from adulteration or misbranding. The ~~Regulatory Agency~~Department may, upon written notice to the owner or person in charge, place a hold order on any milk or milk product which it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, milk or milk products 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 milk or milk products by the ~~Regulatory Agency~~Department, and neither such milk or milk products nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the ~~Regulatory Agency~~Department, except on order by a court of competent jurisdiction.

Adding water to raw milk will be considered a violation of this Regulation if the raw milk contains in excess of three percent (3%) water. A cryoscope shall be used to determine percentage of water by measuring the freezing point of the raw milk. When the freezing point of milk and milk products, other than cultured products, is greater than ~~-0.525~~32.945°~~H~~F (-0.5~~07~~25°C), the farm or plant owner or manager shall be notified that ~~apparently~~ the milk or milk product apparently contains added water. If a second violation of this freezing point standard occurs within two (2) years, ~~an observed~~ milking or ~~operation of~~ processing operations ~~shall~~may be observed, ~~conducted~~ and samples will be collected and analyzed. The freezing point obtained from milk collected during the observation shall be used to determine a definite freezing point standard from the individual farm or plant. A violation of the determined freezing point standard for a specific operation by over three (3%) percent within two (2) years of setting the standard for the individual farm or plant shall call for a two (2) calendar day permit suspension or equivalent.

When milk or milk products ~~is~~ are found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, ~~it~~ they shall be ~~impounded~~ placed under a hold order and additional samples analyzed. Milk or milk products found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals milk or milk products are positive for drug residues, the milk or milk products shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 7126.20). The ~~Regulatory Agency~~Department shall determine the producer(s) responsible for the drug

residue violation and immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale or distribution of milk or milk products containing drug residues, and a penalty shall be imposed. Future pick-ups, sales, or distribution are prohibited until subsequent testing reveals the milk or milk product is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The ~~Regulatory Agency~~Department may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements. The Grade "A" producer's permit may be reinstated, or other action taken, to allow the sale of milk or milk products for human food, when a representative sample taken from the producer's milk or milk products, prior to commingling with any other milk or milk product, is no longer positive for drug residue. Whenever a drug residue test is positive, a recall shall be initiated, and an investigation shall be made to determine the cause. The farm inspection ~~is~~must be completed by ~~T~~the ~~Regulatory Agency~~Department to determine the cause of the residue and actions that must be taken to prevent future violations including:

i. On-farm changes in procedures necessary to prevent future occurrences as recommended by the ~~Regulatory Agency~~Department.

ii. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C~~.~~ of the PMO.

When pasteurized milk or milk products 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 proves the product to be free from adulteration.

b. The following applies in addition to the Administrative Procedures part of Section 2:

When two (2) of the last four (4) samples of a pasteurized product are in violation of the milkfat or milk solids not fat standard for that product a warning letter shall be issued by the Department. When three (3) of the last five (5) samples are in violation, the Department shall suspend the permit.

3. Section 3~~.~~, Permits applies with the following exceptions:

a. The second paragraph on page ~~16~~17 of the PMO, ~~2013~~2019 Revision (paragraph beginning with "Upon notification") shall not apply.

b. The following replaces the entire Administrative Procedures part of Section 3:

ISSUANCE OF PERMITS: Every milk producer, milk product producer, milk distributor, milk products distributor, bulk milk hauler/sampler, milk tank truck[5], milk transportation company, ~~and each~~ milk plant, receiving station, transfer station, and milk tank truck cleaning facility operator shall hold a valid permit prior to beginning operation. No permit shall be issued until all parts of the operation meet the requirements of this regulation. Permits shall not be transferable to other persons/locations or used by a person other than the permit holder. The permit for a milk tank truck(s) may be issued to the milk transportation company. Milk producers who transport milk or milk products only from their own dairy farms; employees of a milk distributor or milk plant operator who possesses a valid permit; and employees of a milk transportation company that possesses a valid permit and transports milk or milk products from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler's permit. Grocery stores, restaurants, soda fountains and similar establishments where milk and milk products are served or sold at retail, but not processed, may be exempt from the requirements of this Section.

While compliance with the requirements for Grade "A" condensed and dry milk products is necessary to receive and retain a permit for these products, it is not the intent of this ~~Ordinance~~Regulation to limit the production of a milk plant that condenses and/or dries milk or milk products~~,~~ to Grade "A" products.

The manufacture of ungraded products for other uses in milk plants operating under a permit for the manufacture of Grade "A" condensed and dry milk products is allowed under conditions specified in Section 7 of ~~this~~ the Ordinance and whereby such products are processed, packaged, and stored separately. In such cases, a second permit is required, which is issued with the understanding that ungraded products shall be handled in such a manner so as to avoid confusion with the Grade "A" production.

Either or both permits may be temporarily suspended for the violation of any applicable provision of this ~~Ordinance~~Regulation or the Ordinance, or revoked for a serious or repeated violation. Suspension of permits for violation of the sanitation Items of Section 7 is provided for in Section 5 of the Ordinance. In addition, the ~~Regulatory Agency~~Department may, at any time, institute court action under the provisions of Section 6 of the Ordinance. There is no specific frequency for the issuance of permits. This should be in accordance with the policies of the ~~Regulatory Agency~~Department and in agreement with those employed for the issuance of permits under this ~~Ordinance~~Regulation.

SUSPENSION OF PERMIT: ~~When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit.~~

~~When the permit suspension is due to violations other than bacterial, coliform, somatic cell, cooling temperature, or drug residue test standards, the permit holder, manager or other authorized representative shall be notified by certified mail or hand delivery of the intent to suspend the permit in thirty days unless a written request for a hearing is filed with the Regulatory Agency. If no request is made in thirty (30) days, the permits shall be suspended until the violations are corrected.~~

The Department may temporarily suspend a permit whenever: it has reason to believe that a public health hazard exists; the permit holder has violated any of the applicable requirements of this Regulation or the Ordinance; the permit holder has violated its permit or an order of the Department, including but not limited to a hold order; the permit holder has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit; or the permit holder exhibits hostile behavior toward a representative of the Department during the performance of its duties. A permit suspension shall remain in effect until any violation has been corrected to the satisfaction of the Department.

The Department may, without warning, notice, or hearing, immediately suspend a permit when, in the opinion of the Department, an imminent health hazard exists. An imminent health hazard may include~~s~~, but is not limited to, a willful refusal to permit authorized inspection, serious or repeated violations of bacterial, coliform, somatic cell, cooling temperature ~~or~~standards, violation of drug residue test standards, or the presence of pathogenic organisms.

Following permit suspension, all manufacturing, bottling, and/or distribution operations shall immediately cease and remain ceased while the permit is suspended. A suspension of the permit shall remain in effect until the violation(s) and any imminent health hazard have been corrected to the satisfaction of the Department.

REVOCATION OF PERMIT: The Department may revoke a permit whenever the permit holder: has committed serious or repeated violations of any of the applicable requirements of this

regulation, the Ordinance, a permit, or an order of the Department, including but not limited to a hold order; or has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit. Notwithstanding any other provisions of this regulation, the permit may be revoked if any Department representative is threatened with bodily harm or physical interference in the performance of inspectional duties.

Following permit revocation, all manufacturing, bottling, and/or distribution operations shall immediately cease and remain ceased.

REINSTATEMENT OF PERMITS: Any permit holder whose permit has been suspended may make written application for the reinstatement of their permit. Any application for the reinstatement of a suspended permit must be in writing and must address all violations underlying the suspension and explain the steps taken to correct those violations.

When the permit suspension has been due to a violation of any of the bacterial, coliform, or cooling temperature standards, the ~~Regulatory Agency~~Department, within one (1) week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard, the ~~Regulatory Agency~~Department may issue a temporary permit whenever a resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7 of the Ordinance. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period. This accelerated sampling applies to bacteria, coliform, somatic cell count, and temperature. The ~~Regulatory Agency~~Department shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of ~~this~~the Ordinance.

Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test, or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one (1) week of the receipt of such notification, the ~~Regulatory Agency~~Department shall make an inspection/audit of the applicant's facility, and as many additional inspections/audits thereafter as are deemed necessary, to determine that the applicant's facility is complying with the requirements. When the findings justify, the permit shall be reinstated.

When a permit suspension has been due to a positive drug residue, the permit shall be reinstated in accordance with the provisions of Appendix N.

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, including previous enforcement, suspension, or revocation history. 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.

4. Section 5~~.~~, Inspection ~~Of~~of Dairy Farms ~~And~~and Milk Plants, applies ~~with the replacement of language in the fifth paragraph on page 22 in the PMO, 2013 Revision with~~in its entirety with the exception of:

~~One (1) copy of the inspection/audit report shall be provided to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and shall be made available to the Regulatory Agency upon request.~~

a. Paragraph 3.c on page 22 in the PMO, 2019 Revision, applies in its entirety with the exception that it shall not apply to milk plants that are not Interstate Milk Shippers (IMS) listed.

b. The fifth paragraph on page 23 in the PMO, 2019 Revision (paragraph beginning with "One (1) copy") is replaced by the following: 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.

c. The last sentence of the first paragraph on page 25 in the PMO, 2019 Revision (sentence beginning with "After receipt of a notice of violation") is replaced by the following: After receipt of an inspection report identifying a violation, but before the allotted time has elapsed, the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station, or distributor shall have an opportunity to request extension of the time allowed for correction.

5. Section 7, Item 7p, Water Supply, applies in its entirety with the addition of the following:

At a minimum, the water system must meet the state requirements for a category 3 small water system.

~~5~~6. ~~Section 15. Enforcement applies with the addition of the following~~The following replaces the language of Section 15, Enforcement, in its entirety:

a. This Regulation is adopted and enforced under the authority of S.C. Code Section 44-1-140 and Section 44-1-150. All applicable provisions of the Ordinance shall be enforced by the Department in accordance with this Regulation and the *Grade "A" PMO*, with Administrative Procedures, current edition, as applicable.

b. Compliance with all provisions of the Appendices adopted in this Regulation shall be deemed a requirement of the Ordinance and this Regulation.

c. Any person found to be in violation of this Regulation or an applicable requirement of the Ordinance, in noncompliance 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.

~~6~~7. The following replaces the language of Section 16~~.~~, Penalty, in its entirety:

Violations shall be punishable in accordance with S.C. Code Section 44-1-150. Each day of continued violation shall be a separate offense.

~~7~~8. Section 17~~.~~, Repeal ~~And~~and Date ~~Of~~of Effect of the PMO, ~~2013~~2019 Revision, shall not apply.

9. Appendix T applies in its entirety with the exception that it shall not apply to milk plants that are not IMS listed.

10. The following additional language applies in accordance with the Footnotes in the Ordinance:

The Department regulates cottage cheese, dry curd cottage cheese, and reduced fat or low-fat cottage cheese under the terms of the Ordinance. The additional provisions specified in Footnotes 7

through 13 for regulatory agencies that regulate such products are hereby adopted and incorporated by reference into the relevant portions of the Ordinance and this Regulation.

Fiscal Impact Statement:

There are no anticipated new costs associated with the implementation of these regulations 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 REGULATIONS:

61-34, Raw Milk for Human Consumption.

Purpose: The Department provides sanitation oversight for the production and sale of raw milk that has not been pasteurized for food safety in South Carolina. The Department is amending R.61-34 to address the further processing and sale of raw milk products, specifically, cream, kefir, and buttermilk, and any additional consumer advisory changes that would be needed for products that receive further processing or become necessary as a byproduct of further processing. The revisions also update raw milk standards as needed to align certain requirements with the 2019 version of the U.S. Food and Drug Administration Pasteurized Milk Ordinance ("PMO").

61-34.1, Pasteurized Milk and Milk Products.

Purpose: The Department provides sanitation oversight of the production and sale of pasteurized milk and milk products for both intrastate and interstate commerce. The Department is adopting requirements of the 2019 PMO through amendment of R.61-34.1. The regulation is currently based on the 2013 PMO and will not meet the federal standards after this year. The amendment of R.61-34.1 to incorporate the updated requirements of the 2019 PMO will enable South Carolina milk producers to continue to meet federal standards and ship milk and milk products for interstate commerce. The Department further provides clarification of requirements for potable water sources.

The Department is also revising R.61-34 and R.61-34.1 for clarity and readability, grammar, punctuation, and codification, and other regulatory text improvement. The amendments to both regulations also include updates to administrative and enforcement provisions.

Legal Authority: 1976 Code Sections 44-1-140(3) and 44-1-150.

Plan for Implementation: The amendments will take legal effect upon General Assembly approval and upon publication in the State Register. Department personnel will then take appropriate steps to inform the regulated community of the amendments. Additionally, a copy of the regulation will be posted on the Department's website, accessible at www.scdhec.gov/regulations-table. Printed copies may also be requested, for a fee, from the Department's Freedom of Information Office.

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

The purpose of R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk Products, is to safeguard public health and provide consumers safe, unadulterated milk and milk products manufactured in South Carolina for sale and distribution in state, and pasteurized milk and milk products sold and distributed both in and out of state. These regulations govern the production, processing, storing, labeling, transportation, and distribution of milk and milk products.

The Department last amended R.61-34 in 2009 and R.61-34.1 in 2015. Since those amendments there have been changes in the milk and milk products industry and numerous revisions to the PMO. The Department's regulations are based on the PMO and, in the case of R.61-34.1, the procedures of the National Conference on Interstate Milk Shippers (NCIMS), specifically Sections VI and VII of the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the NCIMS* and the *FDA PMO, 2019 Revision*, which provide that a state's dairy regulation must be at least as stringent as the PMO to meet requirements for interstate commerce of pasteurized milk and milk products. Updating R.61-34 and R.61-34.1 to the most current amendments of the PMO ensures the regulations reflect current standards and sanitation practices. Furthermore, South Carolina milk producers and processors will be able to continue shipment of milk and milk products in interstate commerce and market their milk products as Grade "A." Updating R.61-34.1 to reflect the current federal standards also serves to reduce administrative burdens on the regulated community by facilitating streamlined inspections and compliance under both state and federal requirements.

The Department is amending the provisions of R.61-34, Raw Milk for Human Consumption, and R.61-34.1, Pasteurized Milk and Milk Products, to incorporate relevant standards of the updated federal ordinance. In addition, the Department is amending the provisions of R.61-34 to incorporate sanitation standards to address the further processing of raw milk for human consumption. These changes serve to make clear those raw milk products that may be produced and sold pursuant to a Department permit and to specify standards for these products to promote clarity and protection of public health.

The amendments to these regulations also include updates to state-specific administrative and enforcement provisions that serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements.

DETERMINATION OF COSTS AND BENEFITS:

There are no anticipated new costs associated with the implementation of these regulations. The amendments will benefit public health by ensuring safe, unadulterated dairy food and dairy food products on the farm, at manufacturing plants, and throughout the distribution chain. The amendments to these regulations also serve to improve the overall clarity and effectiveness of applicable administrative, enforcement, and other requirements. The amendment of R.61-34 and R.61-34.1 will allow the regulations to be in compliance with the most current food safety science regarding milk and milk products. Furthermore, for R.61-34.1 to be in compliance with the FDA Grade "A" Interstate Milk Shippers (IMS) procedures that govern the shipment of milk and milk products across state boundaries, the regulation may not be more than six (6) years behind the current NCIMS procedures and the PMO. By updating selected sections of R.61-34.1 to the 2019 PMO by reference, the regulation will meet this criteria and South Carolina milk producers will be able to continue to ship milk and milk products outside the limits of the state.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Implementation of these regulations will not compromise the protection of the environment or the public health. The regulations will help to ensure that consumers are receiving safe, unadulterated dairy products. The amendment of R.61-34 and R.61-34.1 also provides effective means of reducing the risks of foodborne illnesses at dairy farms and dairy manufacturing plants, thus protecting consumers and industry from potentially devastating public health consequences and financial loss.

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 dairy industry. This could have a detrimental effect on the health of South Carolina's citizens and visitors.

Statement of Rationale:

Here below is the Statement of Rationale pursuant to S.C. Code Section 1-23-110(A)(3)(h):

The Department amends R.61-34 and R.61-34.1 to meet the latest sanitation requirements for providing safe, unadulterated pasteurized and unpasteurized dairy products to consumers and to ensure a comprehensive approach to food safety management in the dairy industry. Furthermore, the amendments to R.61-34.1 satisfy requirements for the shipment of milk and milk products produced under this regulation to be shipped outside the limits of South Carolina.

ATTACHMENT B

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT RESPONSES

Document No. 5033

R.61-34, *Raw Milk for Human Consumption* and R.61-34.1, *Pasteurized Milk and Milk Products*

As of the February 22, 2021, close of the Notice of Proposed Regulation comment period:

Name	Section
Palmatier Farms Dairy	R.61-34, Section VIII

Comment:
I would like to suggest that due to high demand from our consumers here in South Carolina would like to see a cultured milk product added to the regulation 61-34. I would be interested in adding "kefir" to the definition and product list. Since historically the consumption of kefir has been very safe, I think this would be a good product. I think that if we can work on the state level like California to define codes for kefir and "buttermilk" that this would benefit our producers as well as help educate our consumers.

Department Response:
Adopted - The Department has added kefir as an allowed cultured raw milk product pursuant to a permit, including adding a definition in Section I.A.14 and standards in VIII.C. The definition of buttermilk has also been updated to clarify that buttermilk is a cultured raw milk product, and not the byproduct of producing butter.

Name	Section
Samaria Farm & Dairy	R.61-34, Section VIII & Section VI

Comment:
I would like to sell Kefir, I have a lot of customers that are asking for Raw Kefir. Also, on the buttermilk label, I think it needs to say Cultured Buttermilk, if we are not going to be able to sell raw butter.

Department Response:
Adopted - The Department has added kefir as an allowed cultured raw milk product pursuant to a permit, including adding a definition in Section I.A.14 and standards in VIII.C. The definition of buttermilk has also been updated to clarify that buttermilk is a cultured raw milk product, and not the byproduct of producing butter.

In light of these changes, a change was also made to the labeling requirements to clarify that a dairy has the option to add “cultured” to the buttermilk or kefir label in the labeling requirements in VI.F.

Name	Section
Debbie Webster	R.61-34, Section VIII

Comment:
Can Kefir be added to the regs?

Department Response:
Adopted - The Department has added kefir as an allowed cultured raw milk product pursuant to a permit, including adding a definition in Section I.A.14 and standards in VIII.C.

Name	Section
Pete Kennedy, Esq. Weston A. Price Foundation	R.61-34, Section VIII

Comment:
I am an attorney with the Weston A Price Foundation (WAPF), an international nonprofit whose primary mission is to restore nutrient-dense foods to the American diet through research, education, and activism. A goal of WAPF is universal access to raw milk and raw milk products; South Carolina is home to many WAPF members who are raw milk consumers. I have worked on the drafting and development of legislation and regulations regarding the sale or distribution of raw dairy products at the state and federal level over the past 12 years. For over 10 years I worked on foodborne illness outbreaks involving dairy farmers; in recent years the number of foodborne illness outbreaks attributed to raw dairy consumption has declined considerably.

I am writing to request that the Department of Health and Environmental Conservation amend the proposed regulations to allow licensed raw milk producers to sell raw kefir which, as a fluid milk product, is within the scope of 61-34. In the years I worked on foodborne illness outbreaks, I have never heard of an outbreak attributed to the consumption of raw kefir. I have looked at the Centers for Disease Control National Outbreak Recording System (NORS) and could find no data indicating that the consumption of any dairy kefir product, raw or pasteurized, has ever been responsible for a foodborne illness outbreak. Demand for raw kefir has increased in recent years; legalizing its sale could increase revenues for South Carolina raw milk producers.

I am also asking that the department define both "raw buttermilk" and "raw kefir" in 61-34 since the products are so similar in content.

I appreciate your work on the revision of this regulation.

Department Response:
Adopted - The Department has added kefir as an allowed cultured raw milk product pursuant to a permit, including adding a definition in Section I.A.14 and standards in VIII.C. The definition of buttermilk has also been updated to clarify that buttermilk is a cultured raw milk product.

Name	Section
J and J Carolina Kidz Nigerian dwarf goat dairy	R.61-34, Section VIII

Comment:
I am Terri Ayer and own J and J Carolina Kidz Nigerian dwarf goat dairy. Me and my husband sat in on the raw milk for human consumption meeting last week and would really appreciate it if we could add kefir to the raw milk regulations.
At the farmers market we go to each week, we have several customers that would like to purchase kefir. So many individuals are drinking it now for their health. As far as we know from studying this product, it is a safe product and it has many health benefits as well.
It could help increase our weekly sales as another value added product. We believe by adding this to our raw milk regulations it will strengthen our states dairy industry.
We would like to recommend that you offer the addition of kefir to the regulation for this year's legislative session .

Department Response:
Adopted - The Department has added kefir as an allowed cultured raw milk product pursuant to a permit, including adding a definition in Section I.A.14 and standards in VIII.C.