DEPARTMENT OF AGRICULTURE

FOOD PRODUCT INSPECTION

Statutory Authority: 3 Delaware Code, Section 3181 (3 **Del.C.** §3181)

FINAL

ORDER

303 Delaware Raw Milk Regulations

I. NATURE OF THE PROCEEDINGS

Pursuant to its authority under 3 **Del.C.** §3181, the Delaware Department of Agriculture proposed a new regulation regarding fresh milk and raw milk. The purpose of the regulation is to administer and enforce the permitting, testing, and inspection requirements applicable to the sale and distribution of fresh milk, raw milk, and other products derived from raw milk that are intended for human consumption. Other regulations issued by the Delaware Department of Agriculture are not affected by the regulation.

Notice of a public comment period of at least thirty (30) days on the proposed regulation was published in the Delaware *Register of Regulations* for March 1, 2025, in accordance with 29 **Del.C.** §10118(a). This is the Delaware Department of Agriculture's Decision and Order adopting the proposed regulation.

II. FINDINGS AND CONCLUSIONS

1. The public was given the required notice of the Delaware Department of Agriculture's intention to adopt the proposed regulation and was given ample opportunity to provide comments on the regulation.

2. The Department received public comments relating to the overall burden of the regulations with specific references to the need for the required laboratory testing and the potential burden on smaller operations, including herdshares.

3. Having carefully considered the public comments, the Delaware Department of Agriculture has determined that the regulations as proposed appropriately balance protection of public health while limiting impact on business. The Department remains committed to engaging with the regulated community to address specific concerns regarding compliance.

4. Pursuant to 3 **Del.C.** §3181, the Delaware Department of Agriculture has statutory authority to promulgate rules and regulations regarding sale and distribution of raw milk and other products derived from raw milk that are intended for human consumption.

5. The Delaware Department of Agriculture further concludes that it is necessary to promulgate the regulation.

6. The Delaware Department of Agriculture has reviewed the regulation and has determined that, if promulgated, the regulation would have a *de minimis* impact on the State's resiliency to climate change because neither implementation nor compliance with the regulation would reasonably involve the increase in greenhouse gas emissions.

III. DECISION AND ORDER CONCERNING THE REGULATIONS

AND NOW on this 15th day of May 2025, it is hereby ordered that:

1. The proposed Delaware Department of Agriculture regulation is adopted;

2. The text of the final regulation shall be in the form attached hereto as Exhibit A, which remain unchanged as initially published in the March 1, 2025 version of *Delaware Register of Regulations*;

3. The effective date of this Order is ten days from the date of its publication in the *Delaware Register of Regulations* in accordance with 29 **Del.C.** §10118(g); and

4. The Delaware Department of Agriculture reserved to itself the authority to issue such other and further orders concerning its regulations as it deems appropriate.

Wm. Donald Clifton, II
Delaware Department of Agriculture

303 Delaware Raw Milk Regulations

1.0 Statutory Authority and Purpose

This regulation is promulgated pursuant to the authority provided in 3 **Del.C.** §3181, which directs the Department of Agriculture, in consultation with the Department of Health and Social Services, to adopt regulations to administer and enforce the permitting, testing, and inspection requirements applicable to the sale and distribution of fresh milk, raw milk, and other products derived from raw milk that are intended for human consumption.

2.0 Applicability

2.1 This regulation shall be known as the "State of Delaware Raw Milk Regulations".

2.2 The Department may grant a variance by modifying or waiving the requirements of this regulation if, in the opinion of the Department, a health hazard or nuisance will not result from the variance.

3.0 Definitions

The following words and terms, when used in this regulation, have the following meaning:

"**Accredited veterinarian**" means a Category 2 USDA-accredited veterinarian has completed formal training from the National Veterinary Accreditation Program (NVAP) in the state or states in which they are licensed to practice medicine.

"**Approved**" means acceptable to the Department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

"**Approved sampler**" means an individual who has met criteria established by the Department for the sampling of raw milk.

"**Dairy**" or "**dairy farm**" means a place or premise where 1 or more cows or other lactating hooved mammals are kept and a part or all the milk from which is sold or delivered to any person.

"**Department**" means the Delaware Department of Agriculture.

"**Imminent health hazard**" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries and the nature, severity, and duration of the anticipated injuries.

"**Milk-derived product**" means a product other than liquid raw milk made with or containing raw milk, as defined in these regulations, including liquid raw milk that has had flavorings or other ingredients added.

"**Milk Choice Act**" means 3 **Del C.** Ch. 31 Subchapter VI.

"**Permit holder**" means individual or entity that is legally responsible for the operation of the dairy farm.

"**Raw milk**" means fresh milk that is unprocessed, unpasteurized, and unhomogenized, and that is derived from a cow, sheep, or goat.

"**Secretary**" means the Secretary of the Delaware Department of Agriculture.

4.0 Raw Milk Permit

4.1 A raw milk permit authorizes the permit holder to lawfully produce, sell, or distribute raw milk for human consumption. Raw milk must be sold directly to consumers by the permit holder or individuals under the direct supervision of the permit holder (i.e. employees).

4.2 No person may sell or distribute raw milk for human consumption without a valid permit, including those overseeing herd share or other membership or group purchasing arrangements. A valid permit is one that has been approved and issued by the Department.

4.3 Raw milk may only be sold at the location where the milk is produced unless an alternative is approved by the Department.

4.4 Permit Applications

4.4.1 Application Forms

4.4.1.1 Applications will be provided by the Department. The Department may provide the application forms in electronic format.

4.4.1.2 Applications will include fields as determined by the Department.

4.4.2 Application forms must be filled out and returned to the Department along with any documentation required by this regulation.

4.4.3 Permit Renewal

4.4.3.1 Permits must be renewed annually by March 1.

4.4.3.2 The renewal form may include different fields then the initial permit application form and different documents may be required as deemed appropriate by the Department.

4.5 A raw milk permit is not valid if the permit holder is not in significant compliance with this regulation, including the testing and documentation requirements of this regulation. A permit holder shall maintain all records required for compliance with this regulation for at least 3 years and make them available to the Department upon request.

4.6 The Department may suspend or revoke a raw milk permit in accordance with subsection 14.3 of this regulation if the permit holder fails to comply with the permit holder's risk management plan, this regulation, or the Milk Choice Act.

4.7 The Department may determine appropriate training that is necessary to obtain or renew a raw milk permit. The Department may require an applicant to submit training records with the permit holder's raw milk permit application or renewal application.

4.8 The raw milk permit and consumer advisory statement, designed and issued by the Department, shall be posted in a conspicuous place at the point of sale or distribution of the raw milk.

4.9 Raw milk permits are not transferable. Change of ownership may, at the discretion of the Department, require an application for a new raw milk permit.

4.10 The Department shall require a raw milk permit application fee for new permits and at the time of renewal.

5.0 Requirements for Issuance of a New Raw Milk Permit

5.1 For purposes of this regulation, permits are considered new if the dairy has not previously been permitted or if the previous permit has been expired, suspended, or revoked for more than 90 days.

5.2 Before issuing a new raw milk permit, the Department will inspect the dairy farm that is the subject of a new raw milk permit application. The dairy farm must be in substantial compliance with the applicable provisions of the Milk Choice Act, this regulation, and the dairy farm risk management plan to be eligible for a raw milk permit.

5.3 An applicant for a new raw milk permit must provide the Department confirmation that the animal or herd from which the raw milk for human consumption is to be produced has been determined to be free from brucellosis and free from tuberculosis in accordance with the process in Section 9.0 of this regulation. This confirmation shall be provided in writing as part of the application submission for a new raw milk permit.

5.4 An applicant for a new raw milk permit must have a licensed veterinarian examine the animal or herd and provide the Department a written report of this examination. The report must reflect that, upon physical examination, the subject animals are in apparent good health and free from evidence of communicable disease. This shall be done in accordance with Section 9.0 of this regulation.

5.5 Water Testing Requirements

5.5.1 An applicant for a new raw milk permit must have the dairy farm water supply tested to determine compliance with Section 10.0 of this regulation. Satisfactory water results must be provided as part of the application submission.

5.5.2 The testing requirement in subsection 5.5.1 does not apply if the water supply is through a public or municipal water system, but confirmation of the connection to a public or municipal system must be provided in writing as part of the application submission.

5.5.3 The testing requirement in subsection 5.5.1 applies to recirculated cooling water if the dairy farm uses a recirculated cooling water system for milk cooling.

5.6 Milk Testing Requirements

5.6.1 The applicant must have an approved sampler draw 3 separate samples of commingled milk from the bulk tank. The samples must be drawn at least 7 days apart and be taken on an unannounced basis.

5.6.2 The applicant must submit each of the 3 samples described in subsection 5.6.1 to a laboratory approved by the Department for analysis to determine whether the samples meet the standards in Section 11.0 of this regulation.

5.6.3 If any of the 3 analyzed samples described in subsection 5.6.1 violates or exceeds a standard in Section 11.0 of this regulation, with the exception of pathogenic bacteria testing as described in subsection 5.6.4, then the applicant must repeat the 3-sample process until 3 successive samples are in compliance with the referenced standards.

5.6.4 If the first of the 3 required samples concludes that no pathogenic bacteria are present, then the second and third samples need not be tested for the presence of pathogenic bacteria. If a sample test concludes that pathogenic bacteria are present, a raw milk permit will not be issued until 2 separate consecutive tests, from samples drawn at least 7 days apart, conclude that no pathogenic bacteria are present.

5.7 Before the issuance of a new raw milk permit, the Department must complete a plan review as part of the initial application package. The plan review requirements include submission of:

5.7.1 Equipment list.

5.7.2 Floor plan including dimensions of place, equipment layout, and flooring material.

5.7.3 Process flow diagram that shows sanitation, storage, handling, and other activities from milking through sales or distribution.

5.7.4 Testing and sampling plan.

6.0 Renewal of a Raw Milk Permit

6.1 Renewal applications should be submitted on the Department provided forms at least 60 days in advance of permit expiration. Extensions of current permits will not be issued without submission of a renewal application.

6.2 Renewal permit applications must include documentation of any significant changes to facility, processes, or operations.

6.3 Renewal permits will not be issued unless the dairy is in compliance with water testing, milk testing, and animal health requirements of this regulation.

6.4 If the dairy has not been inspected in the 12 months before renewal a new inspection may be required at the discretion of the Department.

6.5 Renewal permit applications must include sales figures in dollars and milk volume for the previous calendar year.

7.0 Risk Management Plan

7.1 An applicant must develop a risk management plan for raw milk production that analyzes milk safety risks present on the farm and practices to reduce, manage, or mitigate those risks. The risk management plan must consider the size and other unique characteristics of the farm when analyzing risks and appropriate practices.

7.2 The risk management plan must address risks and practices including:

7.2.1 Introduction of animals onto the farm.

7.2.2 Herd health.

7.2.3 Milk handling and management.

7.2.4 Environmental risks.

7.2.5 Feed sources.

7.2.6 Human factors.

7.2.7 Nutrition.

7.2.8 Herd management.

7.2.9 On-farm testing procedures and intervals.

7.2.10 Laboratory testing procedures and intervals.

7.2.11 Training.

7.2.12 Documentation of all risk management practices, testing, and training.

7.2.13 Checklists for annual, monthly, weekly, and daily activities.

7.2.14 Protocols the farm shall follow in the event of substandard results, including recall plans.

7.3 The risk management plan must address all requirements of the Milk Choice Act, this regulation, and any additional requirements the Department determines are necessary to protect public health, including additional testing for pathogens and other emerging risks.

7.4 Applicants must submit a copy of the permit holder's risk management plan with the permit holder's application.

7.5 An approved permit holder may revise the permit holder's risk management plan with approval of the Department. Approved plans must be reviewed by the permit holder at least quarterly and updated as required due to change in operations.

7.6 The Department may suspend or revoke a raw milk permit if it determines that the permit holder is not compliance with the permit holder's risk management plan.

8.0 Sanitation

8.1 A permit holder shall maintain and operate the subject dairy operation in compliance with the same sanitation and handling standards that are applicable to the production of milk for pasteurization as set forth in 16 **DE Admin. Code** 4461 State of Delaware Milk Code.

8.2 The provisions of 16 **DE Admin. Code** 4461 State of Delaware Milk Code are incorporated by reference, to the extent they do not conflict with this regulation.

9.0 Animal Health

9.1 A permit holder shall monitor the health of the animals from which the raw milk for human consumption is produced to ensure that they are in general good health and free of tuberculosis and brucellosis.

9.2 A permit holder shall individually identify or mark animals in accordance with 3 **DE Admin. Code** 904.

9.3 A permit holder shall, as part of the permit holder's annual permit renewal, provide the Department confirmation that the animal or herd from which the raw milk is produced has been determined to be free from brucellosis and tuberculosis by tests conducted in accordance with 3 **DE Admin. Code** 904.

9.3.1 An accredited veterinarian shall perform all required testing and provide required documentation.

9.3.2 Testing results shall be linked to individual animals as identified in subsection 7.2 of this regulation.

9.3.3 The interval between tests shall be no more than 13 months.

9.4 A permit holder shall, at intervals of no more than 1 year, have a licensed veterinarian examine the herd and issue a written report of this examination. The report must reflect that, upon physical examination, the herd is in apparent good health and free from evidence of communicable disease. The permit holder shall retain a copy of the written veterinarian's report for at least 3 years and, upon request of the Department, make the report available for inspection.

10.0 Regular Testing of Water Supply

10.1 The water supply for a dairy operation that produces raw milk for human consumption under a raw milk permit must be safe and sanitary.

10.2 The water supply for a dairy operation that produces raw milk for human consumption under a raw milk permit shall be tested at least once every 6 months and whenever any repair or alteration is made to the water supply system. This testing shall be at the permit holder's expense. If the water supply is through a public or municipal water system, this testing requirement does not apply.

10.3 Testing shall be required to determine compliance with the applicable sections of 16 **DE Admin. Code** 4462 Public Drinking Water Systems.

10.4 The water testing described in this section must include bacteriological examinations to determine whether the water is bacteriologically safe. Water is bacteriologically safe if it meets the requirements in Section 8.0 and Section 10.0 of this regulation relating to sanitation; and regular testing of water supply. The requirement of a bacteriologically safe water supply is also applicable to recirculated cooling water if the dairy farm uses a recirculated cooling water system for milk cooling.

10.5 The water supply must contain a Most Probable Number of Coliform Organisms (MPN) of less than 2.2-per-100-milliliters by the multiple tube fermentation method or less than 1-per-100-milliliters by the membrane filter technique or the chromogenic substrate technique.

10.6 The water testing described in this section shall be conducted at a qualified, EPA certified laboratory.

10.7 The permit holder shall retain all records of required water tests for 3 years and make these available for inspection upon request of the Department.

11.0 Regular Testing of Raw Milk for Human Consumption

11.1 On-Farm Testing of Raw Milk

11.1.1 The permit holder may conduct on-farm testing of raw milk using the standards in subsection 11.2.3 of this regulation.

11.1.2 The permit holder's raw milk risk management plan will describe the on-farm tests to be conducted, process for testing, and frequency for each test in accordance with subsection 11.2.3 of this regulation.

11.1.3 On-farm testing of raw milk shall be conducted using equipment and procedures described in the permit holder's raw milk risk management plan and approved by the Department. The permit holder is responsible for all on-farm testing costs.

11.1.4 The testing interval for on-farm testing shall be at least weekly. The Department may require more frequent testing for new permit holders or when the Department determines more frequent testing is necessary.

11.1.5 The permit holder shall create procedures to evaluate and respond to on-farm testing results in the permit holder's raw milk risk management plan. Testing results and actions taken shall be documented by the permit holder.

11.1.6 The permit holder shall maintain records for at least 3 years of all on-farm testing and make those records available to the Department upon request.

11.1.7 Dairies with on farm testing programs approved by the Department may reduce testing required by 11.2.3 of this regulation to once per month with prior approval from the Department.

11.2 Laboratory Testing of Raw Milk

11.2.1 The permit holder shall be responsible to arrange for the regular sampling and testing required with respect to the raw milk permit, and to pay for this testing.

11.2.2 Raw milk samples submitted for testing shall be analyzed at a NCIMS laboratory approved by the Department.

11.2.3 The permit holder shall coordinate the testing of raw milk for human consumption on the following schedule, and the raw milk samples must meet the following standards:

Required Action Interval	**Type of Action or Test Required**	**Standard**
At all times	Maintain raw milk temperature in accordance with raw milk temperature standards.	Raw milk shall be cooled to 40° F (4° C) or less within 2 hours after milking, provided that the blend temperature after the first and subsequent milking does not exceed 50° F (10° C).
At least once each week	Bacterial count	Bacteria may not be present in excess of 20,000 per milliliter. Note: Tested in conjunction with a drug residue/ inhibitory substance test.
At least once each week	Coliform count	Coliform may not exceed 10 per milliliter. Note: Tested in conjunction with a drug residue/ inhibitory substance test.
At least once each month	Somatic cell count	The somatic cell count may not exceed 750,000/milliliter (1,500,000/ml for goat milk).
At least once each month	Test for presence of drugs (including growth inhibitors)	There may be no positive results for drug residue, using drug residue detection laboratory.
At least once each month	Test for the presence of pesticides	No pesticide may be detected at or above actionable levels established for the pesticide by the United States Environmental Protection Agency
At least every 6 months	From a sample drawn from the bulk tank, test for presence of the following pathogenic bacteria: *Salmonellae, Listeria monocytogenes*, *Campylobacter* and *E. Coli* 0157:H7	There may be no pathogenic bacteria present.

11.2.4 The permit holder must maintain testing records for at least 3 years.

12.0 Violations of Raw Milk Testing Standards

12.1 In the event a sample is found out of compliance with the testing requirements in Section 11.0 of this regulation, the producer shall notify the Department immediately upon receipt of the results. The producer shall immediately cease sales or distribution of raw milk.

12.2 Raw milk sales or distribution shall not resume until corrective actions, which may include recalls, additional testing, and other steps as required by the Department, are complete, and the Department has approved the resumption of normal operations.

12.3 Bacterial Count, Somatic Cell Count, Coliform Count or Cooling Temperature Tests

12.3.1 If 2 of the last 4 tested raw milk samples exceed the bacterial count, somatic cell count, or coliform count standards or cooling temperature requirements described in Section 11.0 of this regulation relating to regular testing of raw milk for human consumption, the Department will provide the permit holder with written notice that it is in violation of this regulation and the Milk Choice Act.

12.3.2 If 3 of the last 5 tested raw milk samples exceed the bacterial count, somatic cell count or coliform count standards or cooling temperature requirements in Section 11.0 of this regulation, the Department will proceed to revoke or suspend the raw milk permit, and the permit holder may be subject to additional requirements or actions as specified by the Department.

12.4 Pesticides and Drugs. If a raw milk sample tests positive for the presence of a pesticide at or above actionable levels established for the pesticide by the United States Environmental Protection Agency, or a drug residue in exceedance of FDA allowances, the permit holder shall:

12.4.1 Immediately cease the sale of raw milk for human consumption and notify the Department of the positive test;

12.4.2 Take a second sample and submit it for testing for pesticide residue;

12.4.3 Investigate and determine the cause of the contamination, report the result of that investigation to the Department, and correct that cause of contamination; and

12.4.4 Refrain from selling raw milk for human consumption until the second test shows the sample to be in compliance with this regulation and the Department approves resumption of sales.

12.5 Disease-Producing Organisms. If a raw milk sample tests positive for the presence of pathogenic bacteria or other disease-producing organisms such as *Salmonellae*, *Listeria monocytogenes*, *Camphylobacter*, or *E. Coli* 0157:H7, the permit holder shall:

12.5.1 Immediately cease the sale of raw milk for human consumption and notify the Department of the positive test;

12.5.2 Investigate and determine the cause of the contamination, report the result of that investigation to the Department, and correct that cause of contamination;

12.5.3 Once contamination has been corrected have an approved sampler collect an additional sample, at least 1 day after the previous sample, and submit it to a laboratory approved by the Department for testing for the presence of pathogenic bacteria; and

12.5.4 Refrain from selling raw milk for human consumption until 2 consecutive tests from samples drawn at least 1 day apart show that raw milk produced at the dairy operation sample is meets the standards in Section 11.0 of this regulation and the Department approves resumption of sales.

13.0 Raw Milk Packaging and Consumer Notification

13.1 The Department will consider a milk room facility as being adequate for bottling and capping, or the filling and closure of containers other than bottles. This activity shall be completed in a sanitary manner using easily cleanable equipment that has been cleaned and sanitized.

13.2 Bottles, containers, caps, and closures for raw milk must be sanitized before filling. Bottle and containers may not be filled by the customer.

13.3 Raw milk must be sold in containers owned by the permit holder and labeled according to this Section. Raw milk may not be sold in consumer-owned containers.

13.4 Labels for raw milk containers shall follow 6 **Del.C.** §5118, 6 **Del.C.** §5120, and the requirements in this regulation.

13.5 Labels for raw milk must include the following in a font size where a lowercase "a" is at least 1/16 inch in height, typically a 6-point font size, and in a contrasting color:

13.5.1 The words "Raw Milk;"

13.5.2 The fluid volume;

13.5.3 The name and address of the producer;

13.5.4 The words "Keep Refrigerated"; and

13.5.5 The words "Consumer Advisory Statement" followed by: "The raw milk in this container has not been processed to remove pathogens that can cause illness. The consumption of raw milk may significantly increase the risk of foodborne illness in persons who consume it, particularly with respect to certain highly-susceptible populations such as preschool-age children, older adults, pregnant women, persons experiencing illness, and other people with weakened immune systems."

13.6 Label requirement: Milk Dating

13.6.1 The cap of the raw milk container, or the container itself, must be conspicuously and legibly marked in a contrasting color with the designation of the "sell-by" date-the month and day of the month after which the raw milk may not be sold or offered for sale. The designation may be numerical, such as "8-15", or with the use of an abbreviation for the month, such as "AUG 15" or "AU 15." The words "Sell by" or "Not to be sold after" must precede the designation of the date, or the statement "Not to be sold after the date stamped above" must appear legibly on the container. This designation of the date may not exceed 17 days beginning after midnight on the day on which the raw milk was produced.

13.6.2 The sell-by date must be separate and distinct from any other number, letter, or intervening material on the cap or container.

13.7 Raw milk may not be sold or offered for sale for human consumption after the sell-by date designated on the container.

14.0 Monitoring by the Department

14.1 The Department will periodically sample containers of raw milk for human consumption in the possession of the permit holder. This sampling may occur at any time before the raw milk is delivered to the customer. The Department will take at least 12 samples of raw milk from each permit holder each calendar year. At the discretion of the Department, sampling by the producer may reduce the number of samples collected by the Department.

14.2 The samples described in subsection 14.1 of this regulation shall be analyzed by a laboratory approved by the Department to determine whether bacterial test results exceed the bacterial limits for raw milk described in the Raw Milk Testing Schedule and Standards in Section 11.0 relating to regular testing of raw milk for human consumption before the expiration of the sell-by date designated on the raw milk container.

14.3 When 2 or more samples demonstrate a permit holder cannot produce raw milk for human consumption that remains consistently within the bacterial limits referenced in Section 11.0 of this regulation through the sell-by date marked on the container, the Department may require a permit holder to use a shorter sell-by date or take other action as specified by the Department. The Department will calculate this revised sell-by date so that bacterial growth in the raw milk will not exceed the referenced bacterial limits within that sell-by period if the raw milk is maintained in accordance with the temperature requirements for raw milk in the Raw Milk Testing Schedule and Standards in Section 11.0 of this regulation.

14.4 A permit holder may submit samples to the Department for analysis to obtain approval to resume a specific sell-by period or other requirements imposed by the Department for the raw milk sampled. The Department will approve resumption of a specific sell-by period when analysis of a sample demonstrates that bacterial growth in the raw milk will not exceed the referenced bacterial limits within that sell-by period if the raw milk is maintained in accordance with the temperature requirements for raw milk in the Raw Milk Testing Schedule and Standards in Section 11.0.

15.0 Milk-derived Products

Distribution and sale of raw milk-derived products are not allowed unless considered an allowable product produced in compliance with this regulation.

16.0 Inspection and Sample Collection

16.1 A permit holder shall allow the Department and its personnel to inspect the dairy operation that is the subject of the permit at any time to:

16.1.1 Inspect the farm or facility to determine compliance with this regulation.

16.1.2 Request to review and copy the farm or facility's records pursuant to the State and federal regulations on recordkeeping.

16.1.3 Secure samples for testing and analysis as needed to verify compliance.

16.1.4 Take any other actions the Department deems necessary to comply with responsibilities under the Milk Choice Act or any other applicable statute or regulation.

16.2 Inspection results will be given on an inspection report form provided by the Department.

16.3 If a permit holder fails to allow inspection or sampling by the Department, the Department may revoke or suspend the raw milk permit.

17.0 Enforcement

17.1 Any person or responsible office of that person who violates a provision of this regulation, and any person or responsible officer of that person who is the holder of a permit or who otherwise operates a dairy farm that does not comply with the requirements of this regulation shall be subject to the penalties found in 3 **Del.C.** §3179.

17.2 The Department may take administrative action if it determines that a person is selling or distributing raw milk without a valid permit, that 1 or more conditions exist which represent an imminent health hazard, or that serious violations, repeat violations, or general unsanitary conditions are found to exist.

17.2.1 Operation Without a Permit

17.2.1.1 If a person is found operating without a valid permit as required by Section 4.0 of this regulation, the Department shall immediately order the person to cease the sale of raw milk.

17.2.1.2 The order shall be effective upon receipt by the person selling or distributing raw milk.

17.2.1.3 The order shall remain in effect until a permit application and all requirements of Section 5.0 of this regulation have been received and approved by the Department.

17.2.2 Imminent Health Hazard

17.2.2.1 If a condition is determined to exist which presents an imminent health hazard to the public, the Department may suspend the raw milk permit without a prior hearing. The suspension shall be effective upon receipt of written notice by the person selling or distributing raw milk.

17.2.2.2 A person whose license has been suspended pursuant to subsection 17.2.2.1 may request, in writing, a hearing before the Department at any time during the period of suspension, in order to demonstrate that the imminent health hazard no longer exists. The request for hearing shall not stay the suspension.

17.2.2.3 Whenever, in the opinion of the department, a given supply of raw milk is considered an imminent health hazard, the department may seize, condemn, denature or destroy the milk, without compensation to the owner of the milk.

17.2.3 When conditions exist at a raw milk dairy that represent serious violations, repeat violations or general unsanitary conditions, the Department may suspend or revoke the raw milk permit, initiate a corrective action plan, or schedule a hearing.

17.3 In response to an administrative action by the Department, the producer may:

17.3.1 Take no action, in which case the administrative decision shall remain in effect.

17.3.2 Take action to correct the unsafe and unsanitary practices identified by the Department.

17.3.2.1 The producer may submit evidence showing that the deficient practices identified during the investigation have been addressed and corrected.

17.3.2.2 The Department retains sole discretion to determine if the violations have been corrected.

17.3.2.3 Once violations have been corrected the Department may conduct any follow-up inspections that it deems necessary.

17.3.3 Request, in writing, an administrative hearing in accordance with Section 18.0 of this regulation to contest the administrative decision.

18.0 Violations, Penalties, and Hearing Procedures

18.1 Failure to comply with this regulation may result in the assessment of a civil penalty.

18.2 No civil penalty shall be assessed unless the person has been given notice and opportunity for a hearing on the charge before the Secretary or the Secretary's designee in accordance with 29 **Del.C.** Ch. 101.

18.3 The Department shall notify the person with a violation of this chapter in writing of the date and time of the administrative hearing. The person shall have the right to appear in person, to be represented by counsel, and to provide witnesses in the person's own behalf.

18.4 The Secretary, for the purposes of investigation of a possible violation of this chapter and for its hearings, may issue subpoenas, compel the attendance of witnesses, administer oaths, take testimony, and compel the production of documents. In case any person summoned to testify or to produce any relevant or material evidence refuses to do so without reasonable cause, the Department of Agriculture may compel compliance with the subpoena by filing a motion to compel in Superior Court which shall have jurisdiction over this matter.

18.5 The Secretary or the Secretary's designee shall mail a written decision to the person within 30 days after the conclusion of the administrative hearing. Failure to comply with the 30-day period shall have no effect on the Secretary's decision.

18.6 The Department shall preserve a full record of the proceedings and a transcript may be purchased by any interested person.