

STATE OF NORTH CAROLINA

OFFICE OF THE STATE AUDITOR

BETH A. WOOD, CPA



NORTH CAROLINA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

GRADE "A" MILK

PERFORMANCE AUDIT
JUNE 2017



NCOSA
The Taxpayers' Watchdog

EXECUTIVE SUMMARY

PURPOSE

The objective of this audit was to determine whether the Department of Agriculture and Consumer Services (Department) ensured that entities complied with the standards necessary to meet the Grade “A” milk classification.¹

BACKGROUND

The Department of Agriculture and Consumer Services (Department) is responsible for the enforcement of sanitation requirements designed to keep the Grade “A” milk supply safe for consumers.

North Carolina General Statute Chapter 106 Article 28C requires the Board of Agriculture (Board) to adopt rules relating to the sanitary production, transportation, processing and distribution of Grade “A” milk. The Board adopted the Pasteurized Milk Ordinance (PMO) as its guideline for regulating Grade “A” milk.

The Department is responsible for enforcing the rules governing Grade “A” milk by making sanitary inspections of Grade “A” milk entities, determining the quality of Grade “A” milk, and evaluating methods of handling Grade “A” milk. The Department is also responsible for issuing permits for the operation of Grade “A” milk entities; and suspending or revoking permits for violations in accordance with the rules.

KEY FINDINGS

- The Department is not effectively enforcing the rules governing Grade “A” milk. Specifically, inspections of Grade “A” milk entities are too lenient

KEY RECOMMENDATIONS

- The Department should review the number and types of violations and comments noted by its Grade “A” milk inspectors and evaluate whether its enforcement of the PMO is in line with its regulatory responsibility for consumer protection
- The Department should require its inspectors to document their judgment for not imposing penalties for repeated violations at Grade “A” milk entities

¹ Grade “A” milk means fluid milk and milk products which have been produced, transported, handled, processed and distributed in accordance with the provisions of the rules adopted by the Board of Agriculture.

STATE OF NORTH CAROLINA
Office of the State Auditor



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AUDITOR'S TRANSMITTAL

The Honorable Roy Cooper, Governor
Members of the North Carolina General Assembly
Steve Troxler, Commissioner, North Carolina Department of Agriculture and Consumer Services

Ladies and Gentlemen:

We are pleased to submit this performance report titled Grade "A" Milk. The audit objective was to determine whether the Department of Agriculture and Consumer Services ensured that entities complied with the standards necessary to meet the Grade "A" milk classification.

The North Carolina Department of Agriculture and Consumer Services Commissioner, Steve Troxler, reviewed a draft copy of this report. His written comments are included starting on page 15.

This audit was conducted in accordance with *Article 5A of Chapter 147 of the North Carolina General Statute*.

We appreciate the courtesy and cooperation received from management and the employees of the North Carolina Department of Agriculture and Consumer Services during our audit.

Respectfully submitted,

A handwritten signature in cursive script that reads "Beth A. Wood".

Beth A. Wood, CPA
State Auditor



Beth A. Wood, CPA
State Auditor

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BACKGROUND

The Department of Agriculture and Consumer Services (Department) is responsible for the enforcement of sanitation requirements designed to keep the Grade “A” milk² supply safe for consumers.

North Carolina General Statute Chapter 106 Article 28C requires the Board of Agriculture (Board)³ to adopt rules relating to the sanitary production, transportation, processing and distribution of Grade “A” milk. The Board adopted the Pasteurized Milk Ordinance (PMO)⁴ as its guideline for regulating Grade “A” milk.

The Department is responsible for enforcing the rules governing Grade “A” milk by making sanitary inspections of Grade “A” milk entities, determining the quality of Grade “A” milk, and evaluating methods of handling Grade “A” milk. The Department is also responsible for issuing permits for the operation of Grade “A” milk entities and suspending or revoking permits for violations in accordance with the rules.

The Department’s enforcement of Grade “A” milk is carried out by one compliance officer, one state rating officer, and five milk inspectors who are led by a Dairy Administrator (currently vacant).

At the time of testing, the Department regulated 207 dairy farms, 20 milk processing plants, 288 milk hauler/samplers, 119 plant samplers, 301 milk trucks and 16 single service manufacturers.⁵

² Grade “A” milk means fluid milk and milk products which have been produced, transported, handled, processed and distributed in accordance with the provisions of the rules adopted by the Board of Agriculture.

³ The North Carolina Board of Agriculture is a statutory agency with members appointed by the governor. The Board is a policy and rule-making body that adopts regulations for many programs administered by the Department.

⁴ The PMO is a federal government standard for processing and producing Grade “A” milk and is followed by all 50 states, the District of Columbia and U.S. Trust Territories. This standard was produced by the United States Public Health Service, the Federal Drug Administration (FDA) and other federal and state milk regulator and rating agencies.

⁵ Figures obtained from the Department’s milk inspection database.



OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this audit was to determine whether the Department of Agriculture and Consumer Services (Department) ensured that entities complied with the standards necessary to meet the Grade “A” milk classification.

The audit scope included a review of Department activities between July 1, 2012, and June 30, 2015.

To accomplish the audit objective, auditors interviewed personnel, observed operations, reviewed policies, analyzed records, and examined documentation supporting transactions, as considered necessary. Whenever sampling was used, auditors applied a nonstatistical approach. Therefore, results could not be projected to the population. This approach was determined to adequately support audit conclusions.

Because of the test nature and other inherent limitations of an audit, together with limitations of any system of internal and management controls, this audit would not necessarily disclose all performance weaknesses or lack of compliance.

As a basis for evaluating internal control, auditors applied the internal control guidance contained in professional auditing standards. As discussed in the standards, internal control consists of five interrelated components, which are (1) control environment, (2) risk assessment, (3) control activities, (4) information and communication, and (5) monitoring.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.



FINDING, RECOMMENDATIONS, AND RESPONSES

THE DEPARTMENT IS NOT EFFECTIVELY ENFORCING THE RULES GOVERNING GRADE “A” MILK

The Department of Agriculture and Consumer Services (Department) did not effectively enforce the rules governing Grade “A” milk. Specifically, they were too lenient in their inspections of Grade “A” milk entities. As a result, the Department failed to prevent continued Pasteurized Milk Ordinance (PMO)⁶ noncompliance and extended the period that the public was exposed to potential health risks. The Department believes that their enforcement actions were adequate, however regulations recommend strict enforcement.

Inspections of Grade “A” Milk Entities Too Lenient

Department milk inspectors were lenient in their inspections and failed to prevent continued violation of the PMO. Specifically, inspectors did not suspend milk permits or take other enforcement action when violations of the same requirements were found during two or more successive inspections.

Department milk inspectors used inspection forms that listed conditions the inspector could “check” or mark if the inspector found a violation. The top of the inspection forms stated,

“Inspection of your [entity type] today showed violations existing in the items checked below. You are further notified that this inspection sheet serves as **notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection.**” (*Emphasis Added*)

The forms also provided an area for the inspector’s “remarks.” If the inspector concluded that the deficiencies were not significant enough to be considered violations, the inspector could simply provide written comments and not mark it as a violation.

Inspectors circumvented the requirement to take enforcement action for violations found during two or more successive inspections by using the “remarks” section of the inspection form. Instead, inspectors wrote comments about deficiencies in place of marking them as violations.

Inspectors also failed to suspend milk permits when violations were not corrected by the next inspection.

For the three-year period ending June 30, 2015, auditors reviewed inspection forms and data from 299 active Grade “A” milk entities⁷ in the Department’s milk inspection database and found:

⁶ The PMO is a federal government standard for processing and producing Grade “A” milk and is followed by all 50 states, the District of Columbia and U.S. Trust Territories. This standard was produced by the United States Public Health Service, the Food and Drug Administration (FDA) and other federal and state milk regulator and rating agencies.

⁷ Included review of 2,235 total inspections from dairy farms, 234 inspections of milk processing plants, 107 inspections of single-service manufacturers, 23 inspections of milk haulers and samplers, 27 inspections of plant samplers, and 15 inspections of milk trucks active between July 1, 2012 and June 30, 2015. Active entities are those that were operational during audit scope according to the Department’s milk inspection database.

- 50 instances⁸ where inspectors marked the same deficiency as a violation in two or more successive inspections without suspending the permit. In one case, the inspector marked violations of the same two requirements for six successive inspections without suspending the permit.
- 474 instances where the inspector marked a deficiency as a violation and included comments describing the violation. Then, the inspector wrote the same comments during the next inspection but did not mark the deficiency as a violation. In 66 instances, inspectors alternated between commenting on a deficiency and marking the deficiency as a violation over the span of three or more inspections.
- 457 instances where the inspector wrote comments about the same deficiency during two or more successive inspections but did not mark the deficiency as a violation.

It is reasonable to expect that not every deficiency would be documented as a violation. Department inspectors were expected to exercise professional judgment in determining the significance of observed conditions and whether or not to suspend a permit.⁹ It is also reasonable to expect that an inspector could have decided that some violations did not necessitate permit suspension.

However, from July 1, 2012, through June 30, 2015, the Department almost never suspended an entity's Grade "A" milk permit.¹⁰ Despite entities receiving continued violations or comments, the Department did not document or explain why inspection-related enforcement actions were not taken.

Resulted in Prolonged Exposure to Potential Health Risks

By not taking enforcement actions, the Department failed to prevent continued PMO noncompliance and extended the period that the public was exposed to potential health risks.

For example, potential violations (and related health risks) identified in inspection reports but allowed to continue over two or more inspection periods included, but were not limited to:

- 155 instances related to milking barn, stable, or parlor cleanliness

The PMO states, "A clean interior reduces the chances of contamination of the milk or milk pails during milking. The presence of other animals increases the potential for the spread of disease. Clean milk stools and surcingles reduce the likelihood of contamination of the milker's hands between the milking of one (1) lactating animal and the milking of another."

⁸ An instance contains two or more violations or potential violations at the same entity over two or more inspection periods without enforcement action.

⁹ The PMO states that professional judgement shall dictate whether an observed deficiency rises to the level of a violation based on significance of the deficiency and imminence of a public health hazard.

¹⁰ The Department suspended one permit during a period that included 5,040 inspections of Grade "A" milk entities.

- 114 instances related to insect and rodent control

The PMO states, "Milkhouses should be free of insects and rodents. Surroundings shall be kept neat, clean and free of conditions, which might harbor or be conducive to the breeding of insects and rodents. Insects visit unsanitary places, they may carry pathogenic organisms on their bodies and they may carry living bacteria for as long as four (4) weeks within their bodies, and they may pass them on to succeeding generations by infecting their eggs. Flies may contaminate the milk with microorganisms, which may multiply and become sufficiently numerous to present a public health hazard."

- 98 instances related to milkhouse cleanliness

The PMO states, "Cleanliness in the milkhouse reduces the likelihood of contamination of the milk. The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product-contact surfaces of milk containers, utensils and equipment and other milkhouse equipment shall be clean. Only articles directly related to milkhouse activities shall be permitted in the milkhouse. The milkhouse shall be free of trash, animals and fowl."

Caused by Management's Belief that Its Enforcement Actions Were Adequate

The Department stated that its inspectors performed inspections in accordance with the PMO and that, with some limited exceptions, no warranted enforcement actions have been avoided.

Overall, the Department conducted approximately 5,040 inspections of Grade "A" Milk entities between July 1, 2012, and June 30, 2015.

However, the Department only took one inspection-related enforcement action during that same three-year period.

That enforcement action was taken on an entity with violations related to seven inspection requirements including but not limited to milking barn, stable, or parlor cleanliness; milkhouse construction and facilities; and insect and rodent control. The enforcement action resulted in suspension of the entity's Grade "A" milk permit.

The Department did not provide any documentation that explains why this entity's Grade "A" milk permit was suspended and other entities' permits were not suspended under similar circumstances.

Also Potentially Caused by Conflicting Responsibilities

The lenient enforcement of Grade "A" milk entities may be related to the Department's dual regulatory and advocacy responsibilities.

The responsibility for inspecting Grade "A" milk entities and enforcing the PMO was transferred to the Department on July 1, 2011. This means that the Department is responsible for the enforcement of sanitation requirements designed to keep the milk supply safe for consumers.

On the other hand, the Commissioner of Agriculture is also charged with the improvement of agriculture.¹¹

¹¹ N.C.G.S. 106-22

This dual responsibility is clearly evident in the Department's mission statement, which is:

"To provide services that **promote and improve agriculture, agribusiness** and forests; **protect consumers and businesses**; and conserve farmland and natural resources for the prosperity of all North Carolinians." (*Emphasis Added*)

This dual responsibility can lead to conflict in how these responsibilities are carried out, especially when it comes to regulatory enforcement.

For example, in interviews with auditors, one Department inspector stated "We don't want to run [dairy farms] out of business." And "they [are] losing money." Another Department inspector stated "When times are good, that's when we address a lot of those [violations or potential violations]."

The inherent conflict between the Department's regulatory and advocacy roles has existed for a while. A 2011 Investigative Report of the Department's Standards Division,¹² found the Department was struggling with balancing its regulatory and support responsibilities over the liquefied petroleum gas industry. That report notes that of the 7,466 safety violations noted at 1,189 facilities over a one-year period, only two entities were fined. When explaining the lack of fines, the Division's Director noted that in addition to being regulators, the Department is also a service organization.

Regulations Recommend Strict Enforcement

The PMO recommends that regulatory agencies practice strict enforcement and not seek to excuse violations and defer penalties. Specifically, the PMO states:

"A dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor **shall be subject to suspension of permit and/or court action if two (2) successive inspections disclose a violation of the same requirement.**

Experience has demonstrated that **strict enforcement of the Ordinance leads to a better and friendlier relationship between the Regulatory Agency and the milk industry than does a policy of enforcement, which seeks to excuse violations and to defer penalty** thereof. The sanitarian's criterion of satisfactory compliance **should be neither too lenient nor unreasonably stringent.**

When a violation is discovered, the sanitarian should point out to the milk producer, bulk milk hauler/sampler, industry plant sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor the requirement that has been violated, discuss a method for correction and set a time for correcting the violated requirement.

The penalties of suspension or revocation of permit and/or court action are provided to prevent continued violation of the provisions of this Ordinance but are worded to protect the dairy industry against unreasonable or arbitrary action." (*Emphasis Added*)

¹² [INV-2011-0371](#). North Carolina Department of Agriculture and Consumer Services, Standards Division, Liquefied Petroleum Gas Section

RECOMMENDATIONS

The Department should review the number and types of violations and comments noted by its Grade “A” milk inspectors and evaluate whether its enforcement of the PMO is in line with its regulatory responsibility for consumer protection.

The Department should require its inspectors to document their judgment for not imposing penalties for repeated violations at Grade “A” milk entities.

AGENCY RESPONSE

See page 17 for the Department’s response to this finding.



STATE AUDITOR'S RESPONSE

The Office of the State Auditor (OSA) is required to provide additional explanation when an agency's response could potentially cloud an issue, mislead the reader, or inappropriately minimize the importance of auditor findings.

Generally Accepted Government Auditing Standards state,

"When the audited entity's comments are inconsistent or in conflict with the findings, conclusions, or recommendations in the draft report, or when planned corrective actions do not adequately address the auditor's recommendations, the auditors should evaluate the validity of the audited entity's comments. If the auditors disagree with the comments, they should explain in the report their reasons for disagreement."

In its response to this audit, the Department of Agriculture and Consumer Services (Department) made numerous inaccurate statements. To ensure the availability of complete and accurate information and in accordance with Generally Accepted Government Auditing Standards, OSA offers the following clarifications for the most significant inaccuracies.

US Food and Drug Administration (FDA) Evaluations

The Department's response misleads the reader by implying that the FDA reports¹³ contradict OSA's audit finding about lenient inspections. The Department response also misleads the reader by citing the FDA reports as evidence that no additional enforcement actions are required.

The Department attempts to persuade the reader by focusing attention on the **average** 2017 and 2014 FDA ratings instead of the individual FDA ratings that show state inspectors failed to document significant violations at dairy farms approximately 32% and 26% of the time, respectively.

The Department accurately stated that:

"Enforcement ratings for the NCDA&CS Grade "A" Program have **averaged** 97.5% to 99.8% for the past 6 years for dairy farms and milk processing plants." (*Emphasis added*)

However, the Department's reliance on averages masks the very issue that OSA and the FDA found in the Grade "A" Milk inspection program.

For example, the Department failed to inform the reader that **average** enforcement ratings¹⁴ are derived from **21** individual enforcement method categories – **11** for dairy farms and **10** for milk processing plants. (*See appendices A-D, pages 11-14*)

Furthermore, **nine out of 11** dairy farm enforcement method categories and **eight out of 10** milk processing plant enforcement method categories **were procedural in nature**. The Department should have readily achieved 100% compliance for the procedural type categories. Consequently, it is understandable that the Department achieved an **average** rating of 97.5% to 99.8% when the **average** was derived from ratings that were mostly procedural in nature.

¹³ The Department references the FDA 2014 and 2017 Triennial State Program Evaluations.

¹⁴ An enforcement rating is a measure of the degree to which enforcement provisions of the Grade "A" PMO are being applied by the Regulatory Agency.

Only one of the enforcement method categories actually measured how well state inspectors identified violations and marked them on the inspection sheets. That category was titled "Requirements Interpreted in Accordance With PHS/FDA."

Although the FDA found no significant noncompliance for state inspectors' inspections of milk processing plants, there was significant noncompliance in state inspectors' inspections of dairy farms as shown in table 1 below.

Table 1 – Compliance Rating for "Requirements Interpreted in Accordance With PHS/FDA"

	Dairy Farms	Milk Processing Plants
2017 FDA Report	68.3%	99%
2014 FDA Report	73.6%	98%

The FDA reports note that the compliance score for this enforcement method category is "directly related to longstanding significant violations, including construction, not debited [*not marked*] on the most recent inspection sheet."

In other words, for approximately 32% and 26% of the Dairy Farm inspections that the FDA reviewed, FDA inspectors identified conditions that state inspectors should have marked as a violation on the inspection sheets, **but did not**.

Furthermore, the recommendations and percentage of sanitation violations identified in the FDA reports contradict the Department's assertion that "The enforcement actions of the Grade 'A' Program are adequate."

Specifically, **the 2017 FDA report states:**

"The following **sanitation item was violated by 25% or more** of the forty-one (41) producer dairies visited on the check-ratings during the course of October 1, 2013 through September 30, 2016. **Special attention should be directed toward this item** to improve the overall sanitation of the dairies. [*Emphasis added*]"

	% Farms Check Rated
Item 3: Milking Barn Construction – Cleanliness ¹⁵	29.3%
Item 6: Milkhouse Construction and Facilities – Cleanliness ¹⁵	34.1%
Item 12: Utensils & Equipment – Storage	26.8%
Item 19C,D: Insects & Rodents – Milkhouse openings screened, doors tight, MH free of insects ¹⁵	39.0%

¹⁵ Auditors found several potential violations (and related health risks) identified in inspection reports in these areas. See pages 4-5 of the Finding, Recommendations, and Responses section of this report.

Therefore, while the Department asserts that the FDA reports refute OSA's audit findings and recommendations, the **FDA reports are in fact consistent with OSA's finding and recommendations.**

Huge Toll on the Department

In the Department's response, it discusses the "huge toll" the audit had on Department resources. The response states:

"During the course of this 18-month audit, NCDA&CS personnel have spent more than 2,600 hours assisting OSA staff. The estimated monetary cost for this time is more than \$135,000...additionally, NCDA&CS was forced to suspend routine inspections for a period of time to meet audit response requirements."

This assertion made by the Department lacks context and is misleading.

What the Department fails to say in its response is how the Department's lack of organization and poor record keeping contributed to the "huge toll" on the Department. For example, the Department:

- Was unable to locate more than 4,100 inspection-related documents¹⁶ the Department stated were located in its inspection database
- Determined that the majority of the missing documents were located at inspectors' personal residences (see note below)
- Directed its inspectors to "stop routine work" in order to locate, retrieve, and provide missing documentation to Department management
- Took over 13 months to provide documentation that the Department was charged with safekeeping and was supposed to be readily available
- Is still unable to locate more than 50 documents

NOTE: Since these documents were not scanned in the database and instead located at inspectors' personal residences, evidence and documentation supporting that these inspections ever took place would be lost given the occurrence of a natural or man-made disaster. During the audit, a Department inspector stated "I had all the paperwork. So if my house burns down, that information is gone."

¹⁶ Documents included inspection reports, lab results, permits, warning or suspension letters, and other communication documents.

APPENDIX A: INDIVIDUAL ENFORCEMENT METHOD CATEGORIES FOR DAIRY FARMS
(FDA refers to dairy farms as bulk tank units or BTU's in this evaluation)

Source: 2017 Triennial State Program Evaluation

**REPORT OF ENFORCEMENT METHODS: AVERAGE FOR MILK BTU's
CHECK RATED OCTOBER 1, 2013 THROUGH SEPTEMBER 30, 2016:**

NO.	ITEM	NO. INSP.	NO. COMP.	% COMP.
1	Hold valid permits.	41	41	100%
2	Inspected at least once every 6 months.	41	41	100%
3	Inspection sheets available.	41	41	100%
4	Requirements Interpreted in accordance with PHS/FDA.	41	28	68.3%
5	TB & Brucellosis certification on file.	12	12	100%
6	Water samples tested and reports on file.	41	40	97.5%
7	Milking time inspection program established.	41	41	100%
8	Four samples every six months.	41	41	100%
9	Sampling procedures approved by PHS/FDA methods	12	11.62	96.8%
10	Permit issuance, suspension.... taken as required	12	12	100%
11	Records maintained.	12	11.75	97.9%

NOTE: Minimum State Program Evaluation Requirements for the Dairy Farm Program require a 90% Compliance or greater for items #1. Hold valid permits, #2 Inspection frequency maintained, #6 Water sample frequency maintained, and #8 Product sample frequency maintained. If these program requirements do not meet the minimum requirement of 90%, it should lead to a discussion of corrective action between the FDA and the State, which may include the development and implementation of a Strategic Action Plan. M-I-03-12 (Supplement 1)

The Minimum State Program Requirements for the Dairy Farm Program requiring a 90% compliance or greater have been met.

APPENDIX B: INDIVIDUAL ENFORCEMENT METHOD CATEGORIES FOR MILK PLANTS

Source: 2017 Triennial State Program Evaluation

REPORT OF ENFORCEMENT METHODS: AVERAGE FOR MILK PLANTS CHECK RATED OCTOBER 1, 2013 THROUGH SEPTEMBER 30, 2016:

NO.	ITEM	NO. INSP.	NO. COMP.	% COMP.
1	Hold valid permits.	9	9	100%
2	Inspected at least once every 3 months.	28	28	100%
3	Inspection sheets available.	9	9	100%
4	Requirements Interpreted in accordance with PHS/FDA.	9	8.90	99%
5	Past. Eq. tested at required frequency.	58	58	100%
6	Individual and cooling water samples tested and reports on file.	24	24	100%
7	Samples of products collected at required frequency.	80	80	100%
8	Sampling procedures approved.	9	8.91	99%
9	Permit ... actions taken as required.	9	9	100%
10	Records maintained.	9	8.75	97%

All items from the "Report of Enforcement Methods" were 80% or higher.

APPENDIX C: INDIVIDUAL ENFORCEMENT METHOD CATEGORIES FOR DAIRY FARMS

(FDA refers to dairy farms as bulk tank units or BTU's in this evaluation)

Source: 2014 Triennial State Program Evaluation

**REPORT OF ENFORCEMENT METHODS: AVERAGE FOR MILK BTU's
CHECK RATED OCTOBER 1, 2010 THROUGH SEPTEMBER 30, 2013:**

NO.	ITEM	NO. INSP.	NO. COMP.	% COMP.
1	Hold valid permits.	38	38	100%
2	Inspected at least once every 6 months.	38	38	100%
3	Inspection sheets available.	38	38	100%
4	Requirements Interpreted in accordance with PHS/FDA.	38	28	73.6%
5	TB & Brucellosis certification on file.	12	12	100%
6	Water samples tested and reports on file.	38	38	100%
7	Milking time inspection program established.	38	38	100%
8	Four samples every six months.	38	38	100%
9	Sampling procedures approved by PHS/FDA methods	12	12	100%
10	Permit issuance, suspension.... taken as required	38	38	100%
11	Records maintained.	38	38	100%

Note: Requirements Interpreted in accordance with the Grade "A" PMO as indicated by past inspections had 73.6% compliance for the timeframe of this SPE. Upon review of the Check Ratings, the compliance score is directly related to longstanding significant violations, including construction, not debited on the most recent inspection sheet.

Recommendation: All Grade "A" Milk and Milk Products shall be produced, processed, and packaged to conform to the sanitation requirements of Section 7. The sanitarian's criteria of satisfactory

APPENDIX D: INDIVIDUAL ENFORCEMENT METHOD CATEGORIES FOR MILK PLANTS

Source: 2014 Triennial State Program Evaluation

Item 14p: Storage of SS Articles – 11% of plants check rated

Item 15p(A): Protection from Contamination – 22% of plants check rated

Item 17p: Cooling – 33% of plants check rated

Item 18p & 19p: Bottling & Packaging/Capping – 22% of plants check rated

REPORT OF ENFORCEMENT METHODS: AVERAGE FOR MILK PLANTS CHECK RATED OCTOBER 1, 2010 THROUGH SEPTEMBER 30, 2013:

NO.	ITEM	NO. INSP.	NO. COMP.	% COMP.
1	Hold valid permits.	9	9	100%
2	Inspected at least once every 3 months.	30	30	100%
3	Inspection sheets available.	9	9	100%
4	Requirements interpreted in accordance with PHS/FDA.	9	8.84	98%
5	Past. Eq. tested at required frequency.	92	92	100%
6	Individual and cooling water samples tested and reports on file.	42	42	100%
7	Samples of products collected at required frequency.	98	96	98%
8	Sampling procedures approved.	9	9	100%
9	Permit ... actions taken as required.	9	9	100%
10	Records maintained.	9	8.5	94%

All items from the "Report of Enforcement Methods" were 80% or higher.



RESPONSE FROM THE DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES



Steve Troxler
Commissioner

**North Carolina Department of Agriculture
and Consumer Services**

June 8, 2017

The Honorable Beth Wood
State Auditor
MSC 20601
Raleigh, NC 27699-0601

Madam Wood:

As North Carolina's Commissioner of Agriculture, I take responsibility for ensuring the safety of our food supply very seriously. There is nothing more important in determining the quality of a person's life than the food they eat each day. The Grade "A" Milk Program is an essential part of the North Carolina Department of Agriculture and Consumer Services' (NCDA&CS) commitment to ensuring the safety of the milk supply for North Carolinians.

I have reviewed the audit report issued by the North Carolina Office of the State Auditor (OSA) and respectfully disagree with both the findings and recommendations contained therein. Over the course of the 18-month performance audit conducted by OSA, NCDA&CS has thoroughly reviewed the Grade "A" Milk Program to verify it is effectively evaluating entities involved in Grade "A" milk production to ensure the safety of milk products sold in this state.

As detailed in our response, NCDA&CS has data that refutes OSA's findings and recommendations. The NCDA&CS Grade "A" Milk Program is effectively enforcing the rules governing Grade "A" milk. NCDA&CS' Grade "A" Milk Program has been rated on a regular basis by the U.S. Food and Drug Administration (FDA) and has been determined to be a model national program that consistently achieves high ratings for enforcement actions. (See 2014 and 2017 Triennial State Program Evaluations conducted by FDA.)

Since assuming responsibility for the Grade "A" Milk Program in 2011, NCDA&CS has systematically and proactively initiated several process improvements to enhance the effectiveness of the Program's food safety activities. These process improvements include transitioning from a paper-based to a web-based electronic data collection system and inspection document repository. Improvements also include dedicating the necessary resources to centralized compliance functions. It is worth noting that these process improvements were initiated well in advance of the OSA audit and were executed based on internal program evaluations.

The breadth and scope of this audit, along with the necessary education of OSA staff, has taken a huge toll on NCDA&CS resources, both time and money. During the course of this 18-month audit, NCDA&CS personnel have spent more than 2,600 hours assisting OSA staff. The estimated monetary cost

Ms. Beth Wood

June 8, 2017

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for this time is more than \$135,000. Additionally, NCDA&CS was forced to suspend routine inspections for a period of time to meet audit response requirements.

I am the first to acknowledge that all systems benefit from regular evaluations. NCDA&CS embraces the concept of continuous program improvement, as evidenced by its achieving ISO 17025 accreditation for our Food & Drug Protection Division laboratory as well as successfully implementing FDA Manufactured Food and Animal Feed regulatory program standards. As one of the stewards of public health for this state, NCDA&CS will continue to monitor and improve its programs in meaningful ways. However, the recommendations suggested by the OSA will add minimal value to the public health protection mandates of NCDA&CS.

As noted above, I take my responsibilities seriously to ensure the safety of food products manufactured, distributed and sold in North Carolina. I strongly believe, as set forth more fully in our response, that NCDA&CS has met those responsibilities for our Grade "A" Milk Program.

Sincerely,



Steven W. Troxler
Commissioner

Enclosure

NCDA&CS Grade "A" Audit Response 08Jun2017

Title of Audit Finding

- The Department is not effectively enforcing the rules governing Grade "A" milk. Specifically, inspections of Grade "A" milk entities are too lenient

OSA Recommendations

- The Department should review the number and types of violations and comments noted by its Grade "A" milk inspectors and evaluate whether its enforcement of the PMO is in line with its regulatory responsibility for consumer protection
- The Department should require its inspectors to document their judgment for not imposing penalties for repeated violations at Grade "A" milk entities

Agency Response

NCDA&CS respectfully disagrees with the findings and recommendations of this report.

OSA Finding

The Department is not effectively enforcing the rules governing Grade "A" milk

NCDA&CS Response

NCDA&CS disagrees that the Department is not effectively enforcing the rules governing Grade "A" Milk.

The US Food and Drug Administration (FDA) evaluated, concluded and reported in its Executive Summary of the 2014 and 2017 Triennial State Program Evaluations (SPE) that the "North Carolina Grade "A" NCIMS Program is in compliance with the PMO and the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments*, and its related documents."¹

The Pasteurized Milk Ordinance (PMO) and the *Procedures* are National Conference on Interstate Milk Shipments (NCIMS) Model Documents. They have been adopted by reference by NCDA&CS in the North Carolina Administrative Code. As stated below, compliance with these documents means a state regulatory agency conducts oversight of the production, transportation, processing, handling, sampling, examination, labeling and sale of all Grade "A" milk and milk products to assure a safe supply of milk and milk products.

¹ Copies of the FDA 2014 and 2017 Triennial State Program Evaluations (SPE) are available upon request from the NC Department of Agriculture and Consumer Services, Food & Drug Protection Division at 919-857-4123 or 919-857-4180.

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- Purpose of the *PMO*

"The Grade "A" *PMO*, with Appendices, is recommended for legal adoption by States in order to encourage a greater uniformity and a higher level of excellence of milk sanitation practice in the United States. An important purpose of this recommended standard is to facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce." ²

- Purpose of the *Procedures*

"The *Procedures* is the governing document of the NCIMS and contains the information necessary to maintain a national program that is both uniform and acceptable to the States, U. S. Public Health Service/Food and Drug Administration (PHS/FDA) and the dairy industry. It helps all concerned parties to assure a safe supply of milk and milk products to consumers." ³

FDA also evaluated, concluded and reported in the 2014 and 2017 Triennial SPE that the NCDA&CS is a model NCIMS participant. "This evaluation report is an acknowledgement that the North Carolina Department of Agriculture and Consumer Services is a model National Conference of Interstate Milk Shippers (NCIMS) participant that reflects the principles and the essence of the cooperative nature of the NCIMS. This is largely due to the competence of the Milk Program Manager and the dedication of the Department's staff toward the completion of the health mission."

OSA Finding

Inspections of Grade "A" Milk Entities Too Lenient

NCDA&CS Response

NCDA&CS disagrees that inspections of Grade "A" milk entities were too lenient.

Per the 2014 and 2017 FDA Triennial SPE, Enforcement Ratings for the NCDA&CS Grade "A" Program have averaged 97.5 % to 99.8% for the past 6 years for dairy farms and milk processing plants.

Oversight and regulation of the Grade "A" industry occurs in three tiers.

²A copy of the *PMO* can be accessed at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM513508.pdf>

³A copy of the *Procedures* can be accessed at <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM484776.pdf>

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- Tier one consists of inspections conducted by the state regulatory agency (NCDA&CS) inspectors at dairy farms and milk processing plants.
- Tier two consists of ratings conducted by the Milk Sanitation Rating Officer (SRO) and is based on evaluation of state inspectors' inspections of dairy farms and milk processing plants. The SRO reports a Milk Sanitation Compliance Rating of the dairy farms and milk processing plants plus an Enforcement Rating of the regulatory agency.
- Tier three consists of check-ratings conducted by a FDA Regional Milk Specialist and is based on an evaluation of the inspectors' inspections and the SRO's ratings of dairy farms and milk processing plants. The FDA Specialist reports a Sanitation Rating of the dairy farms and milk processing plants, plus an Enforcement Rating of the regulatory agency.

Ratings are conducted per the NCIMS *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 2015 Revision (MMSR)*.⁴

As defined by the MMSR, the Enforcement Rating is "a measure of the degree to which enforcement provisions of the Grade "A" PMO are being applied by the Regulatory Agency."

FDA reported the following Enforcement Ratings for the NCDA&CS Grade "A" Program in the 2014 Triennial SPE:

October 1, 2010 – September 30, 2013

Average Enforcement Scores (dairy farms)	99.8%
Average Enforcement Scores (milk processing plants)	99.7%

FDA reported the following Enforcement ratings for the NCDA&CS Grade "A" Program in the 2017 Triennial SPE:

October 1, 2013 – September 30, 2016

Average Enforcement Scores (dairy farms)	97.5%
Average Enforcement Scores (milk processing plants)	99.0%

⁴ A copy of the MMSR can be accessed at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/>

OSA statement

"By not taking enforcement actions, the Department failed to prevent continued PMO noncompliance and extended the period that the public was exposed to potential health risks."

NCDA&CS Response

NCDA&CS denies that Grade "A" Program actions exposed the public to potential health risks. This statement is inaccurate and not supported by facts or science.

As stated in the Background section of this report, "The Department of Agriculture and Consumer Services (Department) is responsible for the enforcement of sanitation requirements designed to keep the Grade "A" milk supply safe for consumers." The Department has accomplished that responsibility as evidenced by the Triennial SPE published by FDA in 2014 and 2017 and evidenced by the extensive amount of finished product test results explained below.

NCDA&CS routinely collects samples of finished product (milk and milk products) from every Grade A processing plant in NC per the requirements of the *PMO* (at least 4 samples every 6 months for products specified in the *PMO*). During the scope of this audit (3 years) approximately 3650 samples of finished product were collected and approximately 13,000 tests were conducted for standard plate count (SPC), coliforms, beta-lactams and phosphatase.

During the scope of the audit there was one (1) occurrence at one plant of a finished product sample violation. This one violation consisted of three (3) samples found to contain levels of coliform bacteria above the standard established in the *PMO*. This occurrence resulted in the immediate suspension of the facility's permit to produce this product.

It is noted that this one occurrence represented 0.08% of the finished product samples tested for the three (3) years of the scope of this audit.

Additional test results for the 3650 finished product samples included:

- 0% alkaline phosphatase violations ⁵
- 0% beta-lactam violations ⁶
- 0% standard plate count violations

Additionally, the Centers for Disease Control (CDC) provides data that supports the safety of the milk supply in NC. ⁷

Per CDC there were no reported foodborne outbreaks associated with pasteurized milk products in NC in 1998-2015, which covers the three (3) year scope of this audit plus the

⁵ Alkaline phosphatase is a heat sensitive enzyme in milk that is used as an indicator of pasteurization. <http://www.milkfacts.info/>

⁶ Beta lactams are a class of broad-spectrum antibiotics.

⁷ CDC website for Foodborne Outbreak Online Database (FOOD Tool) <https://www.cdc.gov/foodborneoutbreaks/>

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previous 14 years. It is noted that NC produced 2,865,000,000 pounds of milk during the 3-year scope of this audit (2012 -2015), an average of 955,000,000 pounds per year.⁸

OSA Statement

"Caused by Management's Belief that Its Enforcement Actions Were Adequate"

NCDA&CS response

The enforcement actions of the Grade "A" Program are adequate.

NCDA&CS enforcement actions are evaluated annually by FDA and reported in the Triennial SPE. The SPE dated February 19, 2014 (representing work conducted October 1, 2010 through September 30, 2013) and the SPE dated January 30, 2017 (representing work conducted October 1, 2013 through September 30, 2016) contain the following statement from Anne Reid, Acting FDA Regional Food and Drug Director, Southeast Region.

"This evaluation report is an acknowledgement that the North Carolina Department of Agriculture and Consumer Services is a model National Conference of Interstate Milk Shippers (NCIMS) participant that reflects the principles and the essence of the cooperative nature of the NCIMS. This is largely due to the competence of the Milk Program Manager and the dedication of the Department's staff toward the completion of the health mission."

Additionally, the 2014 and 2017 SPE reported the following evaluation on Enforcement Procedures.

"NCDACS enforcement procedures follow the appropriate sections of the PMO. Review of the state agencies files indicate NCDACS takes appropriate enforcement action when warranted."

OSA statement

"Also Potentially Caused by Conflicting Responsibilities"

NCDA&CS response

NCDA&CS is charged with a variety of different regulatory functions. The milk industry, as regulated by the Grade "A" Milk Program (N.C. Gen. Stat. § 106-266.30, et seq.), is just one of the many industries that NCDA&CS oversees. Other industries that NCDA&CS regulates include, to name a few, the egg industry (N.C. Gen. Stat. § 106-245.13, et seq.),

⁸ USDA National Agriculture Statistics Service, Milk Production report at https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Milk_Production/index.php

food production, manufacturing, wholesale, and retail industries (N.C. Gen. Stat. § 106-120, et seq.), and the meat and poultry industry (N.C. Gen. Stat. §§ 106-549.15, et seq., & 106-549.49, et seq.). NCDA&CS also regulates and controls animal diseases in livestock and poultry (N.C. Gen. Stat. § 106-304, et seq.).

NCDA&CS is not the only agriculture department to regulate Grade "A" milk. Across the country, thirty state agriculture departments have regulatory authority over Grade "A" milk programs.

NCDA&CS' structure is designed to prevent conflicting interests and responsibilities. The regulatory functions of NCDA&CS are separated from marketing and are each organized under different leadership. All of the regulatory duties of NCDA&CS are organized under one Assistant Commissioner, who is responsible for Consumer Protection. Divisions that fall under Consumer Protection include Food and Drug Protection, Emergency Programs, Meat and Poultry Inspection, Standards, Structural Pest Control and Pesticides, and Veterinary. (See Organizational Chart, attached as Exhibit A). Likewise, the Marketing Division, responsible for NCDA&CS' marketing responsibilities, falls under the control of a different Assistant Commissioner. The Marketing Division's purpose, to promote North Carolina's agricultural bounty to consumers across the state, country, and around the world, is removed and separated from NCD&ACS' Consumer Protection mandate. This separation of power over regulatory duties and marketing helps maintain balance and independence within the Department.

Additionally, NCD&CS' structure is not unique. NCD&ACS' structure is similar to that of other federal regulatory programs, such as the United States Department of Agriculture ("USDA"). USDA, like NCDA&CS, has joint responsibility over marketing agricultural products and regulating industry. For example, while USDA's Food Safety and Inspection Service ensures that our nation's meat, poultry and processed egg supply is wholesome, safe, and properly labeled, USDA's Foreign Agricultural Service partners with the U.S. food and agricultural industry to help exporters develop and maintain global markets for hundreds of products. (See <https://www.fas.usda.gov/topics/market-development>.)

The Federal Railroad Administration ("FRA") also has the dual role of both regulating and promoting the rail industry. FRA's Office of Railroad Safety is responsible for ensuring the safety of both our passenger and freight rail network. (See <http://www.fra.dot.gov/Page/P0032>). At the same time, FRA has programs that actively promote the U.S. rail network, such as its High Speed Intercity Passenger Rail Program (see <http://www.fra.dot.gov/Page/P0134>). In short, NCD&ACS' responsibility to both regulate and promote North Carolina agriculture is not unique.

Nonetheless, it is NCDA&CS' policy to educate before we regulate. The purpose in regulating the industry is to gain compliance. NCDA&CS has found that education often brings about compliance more quickly and efficiently than regulator actions, such as civil penalties, lawsuits, or even criminal proceedings. Moreover, the Commissioner has specific statutory authority under N.C. Gen. Stat. § 106-22.6 to take this approach.

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OSA statement

"Regulations Recommend Strict Enforcement"

NCDA&CS response

As stated previously in this response, FDA has evaluated and reported in its Executive Summary of the 2014 and 2017 SPE that the "North Carolina Grade "A" NCIMS Program is in compliance with the PMO and the *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, and its related documents.*"

In addition to the regulatory discretion allowed in the PMO, NCGS §106-22.6, referenced above and set forth below, provides for additional authorities and administrative procedures to achieve compliance with appropriate food safety laws and regulations. The ultimate goal is compliance and ensuring a safe milk supply. As stated above, this is often best achieved through education.

"§ 106-22.6. Exercise of enforcement powers.

When any board, commission, or official within the North Carolina Department of Agriculture and Consumer Services has the authority to assess civil penalties, such authority shall not be construed to require the issuance of a monetary penalty when the board, commission, or official determines that nonmonetary sanctions, education, or training are sufficient to address the underlying violation."

OSA Recommendations

The Department should review the number and types of violations and comments noted by its Grade "A" milk inspectors and evaluate whether its enforcement of the PMO is in line with its regulatory responsibility for consumer protection.

The Department should require its inspectors to document their judgment for not imposing penalties for repeated violations at Grade "A" milk entities.

NCDA&CS Response

NCDA&CS disagrees with the OSA recommendations. As documented within this response, the Department is in compliance with the PMO and is meeting its regulatory obligations to protect the consumers of this state.

NCDA&CS will look to FDA for recommendations for the Grade "A" Program, such as reported in the 2017 SPE. Additionally, reported in the 2017 SPE was FDA's acknowledgement of improvements to the Program since it was transferred to NCDA&CS in 2011.

- "NCDA&CS is staffed with dedicated individuals. This has been demonstrated over the past three years as Senior Environmentalist Health Specialists have assumed the

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- responsibilities of retiring coworkers, assuring that the requirements of the Grade "A" Program were being met. In addition to this extra workload, the senior staff has invested time into the training and education of the new hired Environmentalist Health Specialist.
- The Grade "A" Dairy Program fully complies with the requirements of Appendix N. Regulatory follow-up of antibiotic positive samples and tanker samples has been completed in a timely fashion and well documented.
 - In June 2014 NCDA&CS initiated use of a web-base to track regulatory and compliance activities for all Grade "A" listings. Data on tankers, samplers, haulers, complaints, regulatory letters, contact information, certification information, state ratings, and check ratings are entered by the inspectors and then reviewed/approved by Division Management and/or Compliance. Data is organized chronologically under each firm and can be sorted, organized, and compiled and printed as needed.
 - NCDA&CS added a Compliance Officer position for the Grade "A" Program. The position centralizes Grade "A" data monitoring and compliance activities. The position monitors inspection reports, lab data, and permitting, writes regulatory letters, reviews labels, receives/assigns complaints for follow-up investigation, enters drug residue data into FDA's National Milk Drug Residue Database, assists with development of policies and procedures for the dairy program, and responds to inquiries from the dairy industry, academia and the public.
 - The Program is reporting to the National 3rd Party Data Base as required in the "Procedures".
 - North Carolina continues to address the retirement of critical employees through targeted hiring of experienced individuals."

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This audit investigation required 4,783 hours at an approximate cost of \$488,500.