

*A REPORT BY THE NEW YORK STATE
OFFICE OF THE STATE COMPTROLLER*

**Alan G. Hevesi
COMPTROLLER**



***DEPARTMENT OF AGRICULTURE AND
MARKETS***

DAIRY INSPECTION PROGRAM

2004-S-77

DIVISION OF STATE SERVICES

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Report 2004-S-77

Mr. Nathan L. Rudgers
Commissioner
New York State Department of Agriculture and Markets
10B Airline Drive
Albany, New York 12235

Dear Mr. Rudgers:

The following is our report addressing the Department of Agriculture and Markets' Dairy Inspection Program for the period January 1, 2002 through December 31, 2004.

This audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law. Major contributors to this report are listed in Appendix A.

Office of the State Comptroller
Division of State Services

September 28, 2005

EXECUTIVE SUMMARY

DEPARTMENT OF AGRICULTURE AND MARKETS DAIRY INSPECTION PROGRAM

SCOPE OF AUDIT

The Department of Agriculture and Markets (Department) regulates the dairy industry and monitors the safety of dairy products made or offered for sale in New York State. The Department's Division of Milk Control and Dairy Services (Division) performs periodic inspections of the State's 261 dairy processing plants to determine whether the plants are in compliance with State and Federal sanitary requirements. The Division also takes product samples from the plants and performs laboratory tests to determine whether the samples comply with sanitary standards. In addition, the Division is responsible for investigating consumer complaints about dairy products and for overseeing and certifying the private inspectors who monitor the State's 7,000 dairy farms.

Our audit addressed the following questions about the Division's Dairy Inspection Program for the period January 1, 2002 through December 31, 2004:

- Did the Division perform inspections of dairy processing plants within the required timeframes and in accordance with other State and Federal inspection requirements?
- Did the Division take appropriate action when serious repeat inspection violations were identified, laboratory tests were failed, and consumer complaints were received?
- Did the Division adequately monitor the private inspectors' compliance with their annual certification requirement?

AUDIT OBSERVATIONS AND CONCLUSIONS

We found that dairy processing plants are generally inspected as required. However, more appropriate actions need to be taken by the Division when plants repeatedly fail to comply with sanitary requirements. Improvements are also needed in the Division's monitoring of consumer complaint investigations, and private inspectors' compliance with the annual certification requirement.

We selected a random sample of 20 dairy processing plants and found that the Division's inspections of these plants were generally performed in accordance with requirements, as the inspections were, for the most part, both timely and complete.

If a dairy processing plant fails to meet a sanitary requirement, the plant is expected to take corrective action and may also be fined. If such failures are serious or repeated, the business's operating permit may be suspended. In addition, when a product sample fails a laboratory test, the Division may confiscate the related food products to prevent their sale to the public. We found that the Division rarely took these actions, even when plants repeatedly failed to comply with sanitary requirements and the identified violations could pose a risk to public health.

For example, when we analyzed inspection results at 20 randomly selected plants, we found that the same violation was repeated in consecutive inspections at 17 of the plants. We identified a total of 339 repeat violations at these 17 plants, an average of nearly 20 repeat violations per plant during the three-year period. A total of 51 of the repeat violations (at 7 of the 17 plants) were classified as major - the most serious designation given by the Division. We further determined that samples from these seven plants failed laboratory tests at about the same time as the major repeat violations were identified.

However, the 20 plants in our random sample were rarely fined, and in no instance was an operating permit suspended or the related food products confiscated to prevent their sale to the public. The plants generally were re-inspected within 30 days to determine if corrective actions had been taken, but stronger actions may be needed to bring persistently noncompliant plants into compliance with sanitary requirements. We recommend that stronger actions be taken by the Division when processing plants repeatedly fail to meet sanitary requirements.

We were unable to readily assess the inspection/laboratory test histories of the dairy processing plants. Rather, we had to review individual file folders for each plant to obtain this information, because the Division has not developed effective management information systems for the Dairy Inspection Program. Division managers would be better able to monitor the plants' compliance with sanitary requirements if such information systems were available. We recommend the Division develop these information systems. We also recommend the Division make certain improvements in its monitoring of consumer complaint investigations and private inspectors' compliance with the annual certification requirement.

COMMENTS OF DEPARTMENT OFFICIALS

A draft copy of this report was provided to Department officials for their review and comment. Their comments have been considered in preparing this report and are included as Appendix B. Although officials generally agreed with most of our recommendations, they believe the report contains inaccuracies and misconceptions that do not present a true appraisal of the Dairy Inspection Program's effectiveness. Appendix C is the State Comptroller's Notes to the Department's response.

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INTRODUCTION

Background

The dairy industry is the single largest segment of New York's agricultural industry, and New York ranks third among the states in the production of dairy products. Milk is the most basic dairy product, and in 2003 (the most recent year that statistics were available), New York's dairy industry produced 11.9 billion pounds of milk, with a value of \$1.5 billion. There are about 7,000 dairy farms and 261 dairy processing plants in New York State.

The Department of Agriculture and Markets (Department) regulates the dairy industry and monitors the safety of dairy products made or offered for sale in the State. These functions are performed by the Department's Division of Milk Control and Dairy Services (Division). The Division's objectives are to protect the health of New Yorkers and promote the economic development of the State's dairy industry. To achieve these objectives, the Division establishes various controls and administers various programs, often in conjunction with Federal and other State agencies.

Businesses involved in the handling, processing, distribution and sale of milk products must be licensed by the Division, and are subject to on-site audits and inspections performed by the Division. The businesses are required to comply with various financial, marketing and sanitary requirements, and the Division uses the audits and inspections to assess the businesses' compliance with these requirements.

Compliance with sanitary requirements is assessed in the Division's Dairy Inspection Program. Compliance is assessed through sanitary inspections of the businesses and analyses of food samples taken from the businesses.

Sanitary inspections are performed by Division inspectors and private inspectors who are certified and overseen by the Division. Dairy processing plants and other businesses are inspected by Division inspectors, while dairy farms are inspected by certified inspectors. The inspections are to be

performed within certain prescribed intervals (e.g., processing plants are to be inspected every 90 days) and in accordance with certain prescribed standards and procedures. These standards and procedures are contained in an inspection manual (Manual) that was developed by the Division and in Federal regulations known as the Grade "A" Pasteurized Milk Ordinance (PMO).

If violations are found during an inspection, the business is expected to take corrective action and may also be fined. If the violations are significant, the business is to be re-inspected within 30 days to verify that corrective actions were taken. If serious or repeated violations are found, the business's operating permit may be suspended. If the violations are sufficiently serious, the operating permit may be revoked.

Samples of milk and other dairy products are to be taken from processing plants and other businesses for laboratory analysis. The samples are to be taken at certain prescribed intervals, which vary by product (e.g., at least four samples of milk must be taken from each plant every six months). The samples are to be tested against various standards, such as the amount of bacteria allowable. The tests may be performed by regional Department laboratories or the Department's Food Laboratory in Albany.

If a product sample fails a test, the plant is expected to take corrective action and may also be fined. If test failures are serious or repeated, the business's operating permit may be suspended. If test failures are sufficiently serious, the operating permit may be revoked. In addition, when a product sample fails a test, the Division may confiscate the related food products to prevent their sale to the public.

The Division, as a member of the National Conference on Interstate Milk Shipments, is required to enforce compliance with the PMO. If the Division's Dairy Inspection Program were not in substantial compliance with the PMO, the dairy processing plants in New York would not be allowed to freely ship their milk and milk products to other states. In its most recent evaluation of the Dairy Inspection Program, which covered the 2000 and 2001 calendar years, the Federal Food and Drug Administration determined that the Division was in compliance with the PMO.

The Division employs a total of 42 inspectors (also called Dairy Product Specialists). The Division divides the State into five dairy regions, and the inspectors are responsible for performing inspections and overseeing private certified inspectors in each region. The inspectors are also responsible for investigating consumer complaints about dairy products. During the three years ended December 31, 2004, a total of 290 such complaints were received by the Department.

Audit Scope, Objectives and Methodology

We audited the Dairy Inspection Program for the period January 1, 2002 through December 31, 2004. The objectives of our performance audit were to determine whether the Division:

- performed inspections of dairy processing plants within the required timeframes and in accordance with other inspection requirements in the Manual and the PMO;
- took appropriate action when serious repeat inspection violations were identified, laboratory tests were failed, and consumer complaints were received; and
- adequately monitored private inspectors' compliance with the Division's annual certification requirement.

To accomplish our audit objectives, we reviewed applicable laws, rules, regulations, policies and procedures. We also interviewed Division officials, and reviewed and analyzed records and reports maintained by the Division. We reviewed inspection reports on file for all 261 dairy processing plants that were active at the time of our audit. In addition, we randomly selected 20 of these plants for a more detailed review of inspection reports, laboratory test results and actions taken by the Division in response to serious repeat inspection violations and failed laboratory tests. Additional details about our sampling methodology are provided later in this report. We also reviewed Division records relating to consumer complaints and the training provided to certified inspectors.

We conducted our audit in accordance with generally accepted government auditing standards. Such standards require that we plan and perform our audit to adequately assess those Department operations included within the audit scope. Further,

these standards require that we understand the Department's internal control structure and compliance with those laws, rules and regulations that are relevant to the operations included in our audit scope. An audit includes examining, on a test basis, evidence supporting transactions recorded in the accounting and operating records and applying such other auditing procedures as we consider necessary in the circumstances. An audit also includes assessing the estimates, judgments and decisions made by management. We believe our audit provides a reasonable basis for our findings, conclusions and recommendations.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State, several of which are performed by the Division of State Services. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. In addition, the Comptroller appoints members to certain boards, commissions, and public authorities, some of whom have minority voting rights. These duties may be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these management functions do not affect our ability to conduct independent audits of program performance.

Comments of Department Officials

A draft copy of this report was provided to Department Officials for their review and comment. Their comments have been considered in preparing this report and are included as Appendix B. Although officials generally agreed with most of our recommendations, they believe the report contains inaccuracies and misconceptions that do not present a true appraisal of the Dairy Inspection Program's effectiveness. Appendix C is the State Comptroller's Notes to the Department's response.

Within 90 days after final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department of Agriculture and Markets shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and

where recommendations were not implemented, the reasons therefor.

INSPECTIONS AND LABORATORY TESTS

We found that sanitary inspections of dairy processing plants are generally performed in accordance with requirements, as the inspections are, for the most part, both timely and complete. However, more appropriate actions need to be taken by the Division when plants repeatedly fail to comply with sanitary requirements. We found that, while such plants generally were re-inspected within 30 days, they were rarely fined and almost never had their operating permits suspended. Further, when sampled items exceeded allowable bacterial levels in Department laboratory tests, the related food products generally were not confiscated to prevent their sale to the public.

If the processing plants in the State were generally in compliance with sanitary requirements and if repeat violations were rare, the Division's lenient enforcement practices might be appropriate. However, we found that it is not unusual for plants to have significant violations and not unusual for violations to be repeated. To give these noncompliant plants more incentive to improve their operations, we recommend the Division take stronger actions in response to significant and repeated sanitary violations.

We were unable to readily assess the inspection/laboratory test histories of the dairy processing plants. Rather, we had to review individual file folders for each plant to obtain this information, because the Division has not developed effective management information systems for the Dairy Inspection Program. Division managers would be better able to monitor the plants' compliance with sanitary requirements if such information systems were available. We recommend the Division develop these information systems.

Plant Inspections

According to the Manual and the PMO, dairy processing plants must be inspected at least once every 90 days, unless significant violations were detected in the last inspection. If significant violations were detected in the last inspection, the

next inspection (a re-inspection) must be performed within 30 days.

In addition, to comply with the requirements contained in the Manual and the PMO, plant inspections must be complete. The inspectors must examine certain aspects of plant operations and determine whether these operations meet certain specified requirements. For example, inspectors must examine each plant's bulk cooling charts, which record the temperatures maintained for chilled milk products, and verify that the temperatures did not exceed certain maximum allowable levels. To ensure completeness, the inspectors use a checklist that contains all the prescribed inspection procedures.

If a dairy processing plant fails to meet the prescribed standards of sanitation, public health may be threatened. Salmonellosis, staphylococcal/streptococcal infections, and other types of infections may be transmitted through improperly processed dairy products, and can result in scarlet fever, septic sore throat or severe gastroenteritis. It is therefore critical that sanitary inspections of processing plants be both timely and complete.

To determine whether the Division's sanitary inspections of processing plants were performed within the required timeframes and were complete, we examined the inspection reports on file at the Division for a random sample of processing plants. We randomly selected 20 of the 261 plants that were active at the time of our audit, and examined the inspection reports on file for all 244 inspections and re-inspections that were performed at these 20 plants during the three years ended December 31, 2004.

We found that, in general, the inspections were performed within the required timeframes and were complete. While we identified some instances in which inspections were not performed within the required timeframes, these instances were relatively infrequent and were not significant.

Automated tracking systems are often used to monitor the performance of activities such as plant inspections. With the use of these systems, expected completion dates can be compared against actual completion dates, and corrective action can be initiated when activities, such as inspections, are in danger of being late. However, the Division has no tracking system for the plant inspection process. Instead, the Division

relies on individual supervisors in each region to keep the process timely. While our review indicates that the process has been timely, it may not necessarily continue to be so in the future when personnel and circumstances change. We therefore recommend that a tracking system be developed for the plant inspection process.

Repeat Inspection Violations

If significant violations are identified during a sanitary inspection, certain actions may be taken by the Division. For example, the Division may perform a re-inspection of the plant, fine the plant, suspend the plant's operating permit, or revoke the plant's operating permit. Guidelines in the Manual indicate how violations are to be classified and assessed, and in what circumstances these actions are to be taken.

Using the checklist of prescribed inspection procedures, the Manual classifies each possible violation on the checklist as either incidental, minor or major. For example, if the inspector finds a hole in the floor of the plant, the violation is classified as incidental; however, if the inspector finds that pasteurization requirements have not been met, the violation is classified as major. On the basis of these classifications, one of four possible inspection ratings is to be given to the plant, as follows:

- Category 1 - Only incidental violations, or no violations at all, are identified. The plant is in substantial compliance with sanitary requirements, and a letter does not need to be sent to the plant superintendent affirming the need for corrective actions.
- Category 2 - Incidental and/or minor violations are identified. The plant is in substantial compliance with sanitary requirements, but the violations are such that a letter should be sent to the plant superintendent affirming the need for corrective actions.
- Category 3 - Significant violations (major violations or a serious combination of minor violations) are identified. The plant needs to be re-inspected within 30 days to verify that corrective actions have been taken.
- Category 4 - The violations are so critical that the plant's operating permit must immediately be suspended or

revoked. According to the Manual, a plant should receive this rating “only when it is the opinion of the Specialist [inspector] that extraordinary action is needed.” (The Manual cites violations of pasteurization requirements or very dirty equipment as possible reasons for taking this action.) The Division’s Central Office must be notified before this action is taken. The permit will not be re-activated/re-issued until the plant has been satisfactorily re-inspected.

(In addition, a Category 5 rating may be given to a seasonal plant or a year-round plant that has voluntarily suspended its operations. This rating indicates that the plant has a valid operating permit, but does not need to be inspected again in 90 days, because it has temporarily suspended its operations.)

Plants may also be fined for violations. Generally, fines are levied only for major violations, and not all major violations are fined. There are no guidelines in the Manual regarding fines; rather, senior Division officials in the Central Office are responsible for deciding whether a plant will be fined, and the officials use their judgment in making this decision. If a fine is being considered by these officials, they send a letter to the plant giving the superintendent an opportunity to respond to the inspector’s findings.

Thus, in most instances, no significant action is to be taken by the Division when a plant receives a category 1 or 2 rating, because such plants are in substantial compliance with sanitary requirements. However, significant action is to be taken when a plant receives a category 3 or 4 rating, because such plants are not in substantial compliance with sanitary requirements. Plants with a category 3 rating must be re-inspected within 30 days and may also be fined; plants with a category 4 rating must have their operating permit suspended or revoked and may also be fined.

We note that the Division abides by the Manual, which is more lenient than the PMO, with respect to violations. According to the PMO, because of the public health risks associated with improperly processed milk products, all violations cited in an inspection report are considered major (there are no minor or incidental violations), and a plant may have its permit suspended or revoked if *any single violation* is repeated in two or more consecutive inspections. Thus, a plant that could have

its permit suspended or revoked under the PMO because of repeated violations, could receive a category 1 or 2 rating under the Manual and not be penalized at all, if the repeated violations were classified by the Manual as incidental or minor.

While the Division may not take significant action when repeat violations are classified as incidental or minor, it is required by the Manual to take some kind of action when repeat violations are classified as major. To determine whether the Division took appropriate actions when the same major violation was found in two or more consecutive inspections, we reviewed the actions taken by the Division in such circumstances. Since the Division has no comprehensive database of inspection information, we could not readily identify the inspections in which major repeat violations were identified. Instead, we had to examine a sample of individual inspection reports to identify such instances.

We thus examined the inspection reports that were on file for our random sample of 20 processing plants. A total of 244 reports were on file for these plants for the three years ended December 31, 2004. We examined these 244 inspection reports and identified a total of 51 instances, relating to 7 of the 20 plants, in which the same major violation was found in at least two and as many as five consecutive inspections.

We then reviewed the actions taken by the Division in these 51 instances. We found that, in all 51 instances, a re-inspection was performed within 30 days, as required by the Manual. However, in only 5 of the 51 instances was a fine assessed (the fines totaled \$1,000), and in no instance was an operating permit suspended or revoked.

In most of the 51 instances, the major repeat violations involved unclean and/or contaminated containers and equipment, or inadequate cooling of milk and milk products. For example, the following major violations were identified in two or more consecutive inspections:

- Black mildew or mold growth was present in processing areas.
- Plants did not properly record when storage tanks were washed, emptied or filled.
- Bulk tank cooling charts either were not available or did not

provide assurance that product temperatures remained below the maximum temperatures allowed by the PMO.

The PMO notes that containers, utensils and equipment in dairy processing plants must be thoroughly cleaned if public health risks are to be avoided. Even a very small number of disease organisms in residue films left on milk contact surfaces can grow to dangerous proportions.

We question whether the actions taken by the Division in these 51 instances were sufficient. While the actions complied with the guidelines in the Manual, these guidelines may not be commensurate with the potential risks to public health, and thus may be too lenient. The PMO allows the states to be more or less lenient in their assessment of penalties, and we believe New Yorkers would be better protected against public health risks if the Division were less lenient.

For example, we reviewed the inspection reports on file for all 261 processing plants that were active at the time of our audit to determine how many of these plants received a category 3 or category 4 rating during our three-year audit period. We found that none of the inspections resulted in a category 4 rating, and thus a suspension or revocation of the plant's operating permit. Consequently, the strongest action taken by the Division during our three-year audit period was to levy fines, and it appears that this was done infrequently.

If the processing plants in the State were generally in substantial compliance with sanitary requirements and if repeat violations were rare, the Division's lenient enforcement practices might be appropriate. However, we found that it is not unusual for processing plants to have significant violations and not unusual for violations to be repeated, as follows:

- When we reviewed the plant inspection reports that were on file for our audit period, we found that 96 of the 261 plants (37 percent) had at least one category 3 rating during the three-year period. Therefore, on at least one occasion during this period, more than one-third of the dairy processing plants operating in New York State had significant violations (i.e., major violations or a serious combination of minor violations) that kept them from being in substantial compliance with sanitary requirements at the time an inspection was performed.

- When we analyzed inspection results at the 20 randomly selected plants, we found that the same violation was repeated in consecutive inspections at 17 of the plants. We identified a total of 339 repeat violations at these 17 plants, an average of nearly 20 repeat violations per plant during the three-year period. As was previously noted, 51 of the 339 repeat violations (at 7 of the 17 plants) were classified as major.

The high frequency of significant and repeat violations indicates that the Division's lenient enforcement practices are not always appropriate and, in some instances, stronger actions may be needed. In particular, stronger actions may need to be taken in response to repeat violations, as re-inspections and the occasional fine may not give noncompliant plants enough incentive to improve their operations. We therefore recommend that the guidelines in the Manual be revised so that stronger actions are taken (e.g., fines and suspensions) when plants repeatedly fail to comply with sanitary requirements. We further recommend that the Division track each plant's inspection performance and take appropriate action when repeat violators fail to improve their performance.

Failed Laboratory Tests

The Division may also take certain actions when a product sample fails one of the Division's periodic laboratory tests. In all such instances, the Division is to inform the plant of the failure and ask that it be investigated. In addition, the Division may also perform a follow-up sanitary inspection of the plant, take a follow-up sample within 21 days, fine the plant, suspend the plant's operating permit, or revoke the plant's operating permit. The Division may also confiscate the related food products to prevent their sale to the public.

The Manual contains guidelines that describe when follow-up sanitary inspections and follow-up samples are required (e.g., when a product has failed two of the last four laboratory tests). The Manual also specifies the circumstances in which related food products *must* be confiscated (generally, when a product has failed three of the last five laboratory tests). However, the Manual contains no guidelines for determining whether a fine should be levied or an operating permit should be suspended or revoked when a product sample fails a laboratory test. These

actions may be taken, but they are taken at the discretion of senior Division officials in the Central Office. Similarly, food products may be confiscated in circumstances other than those specified in the Manual, but such confiscations are made at the discretion of senior Division officials in the Central Office.

To determine whether the Division took appropriate actions when product samples failed laboratory tests, we reviewed the actions taken in response to certain test failures at the 20 randomly selected plants. We reviewed all the laboratory test results on file for these 20 plants for the three years ended December 31, 2004 (according to Division officials, some test results were not on file because the records had been misplaced during the Department's move to a new building), and identified a total of 102 instances in which a product sample failed one or more tests (we also identified 2,639 instances in which a product sample passed all of its tests). We determined that, in 49 of these 102 instances, the sample failed a test at about the same time as a sanitary inspection at that plant identified a major repeat violation. Since these 49 test failures did not appear to be isolated incidents of noncompliance on the part of these plants, we reviewed the actions taken by the Division in these 49 instances, which related to 7 of the 20 plants.

We found that the Division's responses to these 49 test failures complied with the requirements contained in the Manual. For example, in all 49 instances, the Division informed the plants of the test failures and asked that the failures be investigated. However, the files contained no documentation indicating that the Division followed up with the plants to determine whether the failures were in fact investigated and appropriate corrective action was taken. We recommend that such follow-up action be taken and documented. In the absence of this follow-up, plants may be less likely to perform the investigations and correct the problems.

We also found that, in most instances, additional discretionary actions were not taken by the Division (e.g., fines, suspensions or confiscations). In only 2 of the 49 instances was a fine assessed (the fines totaled \$1,800), and in no instance was an operating permit suspended/revoked or the related food products confiscated to prevent their sale to the public.

In responding to our report, the Department indicated that instances where products were not confiscated did not pose a threat to public health. However, in 12 of the 49 test failures, the test results were especially worrisome, as follows:

- Three samples had coliform (a particular type of bacteria) counts between 35 and 75 times the level deemed acceptable. Excessive coliform counts are an indicator of unsanitary conditions that may be associated with disease-causing pathogens such as E.coli.
- One milk sample contained twice as much Vitamin D as is allowed. In the letter sent to the plant reporting the test results, the Division stated that this level of Vitamin D may be toxic to the consumer.
- Eight samples contained approximately 20 to 80 times the level of aerobic bacteria deemed acceptable, which indicates that the products were at or nearing spoilage.

The product samples in these 12 test failures were taken from four different plants. These 12 instances included the two cases where the Division assessed fines totaling \$3,600, but were reduced to \$1,800.

Furthermore, although the Department's guidelines state that products must be confiscated if a plant fails three out of five consecutive tests, we noted instances where this rule was not enforced. For example, one plant failed three out of five tests on three separate occasions, occurring in October 2002, May 2003 and November 2004, yet was only fined \$300, \$600, and \$300, respectively. No food products were confiscated. In each case, the Department suspended the plant's operating permit, but immediately issued a temporary permit for it to continue operating.

We question whether the actions taken by the Division in response to these 49 test failures were sufficient. In particular, we question why the related food products were not confiscated to prevent their sale to the public. Small and infrequent fines may not provide effective deterrence against unsanitary practices. Since these 49 test failures occurred at about the same time as a major repeat plant inspection violation, we conclude that the Division's lenient enforcement practices have not been effective with these plants.

We recommend the Manual be revised so that stronger actions are taken when plants repeatedly fail laboratory tests. For example, product confiscations should be required in such circumstances. We further recommend that the Division track each plant's performance on laboratory tests and take appropriate action when repeat violators fail to improve their performance.

We also note that the payment of fines is not adequately recorded in the Division's records. The Division maintains a ledger for its fines, and this ledger indicates that some of the fines have been paid. However, the payment date is not recorded and the amount actually paid is not recorded (fines are sometimes reduced by the Division; for example, the fines in our sample initially totaled \$4,500, but were reduced to \$2,700). We recommend that a full record of fine payments be maintained. Such payments could be recorded on the tracking system we have recommended for laboratory tests. The follow-up actions taken by the Division in response to test failures could also be recorded on this system.

Just as the Division has no comprehensive database of inspection information, it also has no comprehensive database of laboratory test information. Consequently, we had to review individual plant files to obtain information about laboratory test results. Division managers would also have to review these files if they sought information about test results.

For example, reports from the Department's Food Laboratory informed the Division that, during our three-year audit period, the product samples sent to that laboratory had excessive amounts of bacteria in about six percent of the tests performed. However, when we asked Division officials which plants had these test results and what corrective actions were taken at these plants, the officials were unable to tell us; they would have had to review each individual plant file to identify the plants, and there is no source of information for corrective actions since such actions are not routinely documented. If the Division is to effectively manage the Dairy Inspection Program, it needs adequate management information systems. The development of comprehensive tracking systems for inspections and laboratory tests would help meet this need.

Recommendations

1. Develop an automated system for tracking sanitary inspections at dairy processing plants. Use the system to ensure that inspections are performed on time, appropriate penalties are assessed for violations, penalties are increased when violations are repeated, and all fines are paid.

(Department officials responded that they have initiated the development of an automated system for tracking dairy plant inspections.)

2. Develop an automated system for tracking laboratory tests for dairy processing plants. Use the system to ensure that tests are performed on time, corrective actions are taken when tests are failed, appropriate penalties are assessed for failures, penalties are increased when failures are repeated, and all fines are paid.

(Department officials responded that they have initiated the development of a system integrating the Food Laboratory testing system with other regulatory Divisions.)

3. Revise the Manual so that stronger actions are required from the Division in response to repeated violations and test failures. In particular, require that products be confiscated when samples fail laboratory tests.

(Department officials disagree with this recommendation, indicating that enforcement is done in the central office to ensure uniformity and appropriate response based on the public health risks.)

CONSUMER COMPLAINTS AND ANNUAL CERTIFICATION

We examined a random sample of 50 consumer complaints and found that most of the complaints were handled appropriately by the Division. However, in some instances, either the complaint itself was not properly documented or the investigation of the complaint was not documented at all. As a result, we could not determine whether these complaints were handled appropriately. We recommend that all complaint documentation be maintained as required and the complaint handling process be monitored to provide assurance all complaints are handled in an appropriate manner. We also found that improvements are needed in the Division's monitoring of private inspectors' compliance with their annual certification requirement.

Investigation of Consumer Complaints

The Division is responsible for investigating consumer complaints about dairy products sold in New York State. The complaints are initially processed in the Division's Central Office and are investigated by inspectors in the appropriate dairy regions.

According to the Manual, each complaint should be recorded on a prescribed intake form to ensure that the nature of the complaint is fully documented. In addition, each complaint should be investigated, unless the complaint involves product tampering (such complaints are referred to the appropriate police department). Each investigation should be documented, the documentation should be attached to the complaint intake form, and both the form and the documentation should be retained in Division files.

To determine whether consumer complaints were handled in the manner required by the Manual, we randomly selected for review 50 of the 290 complaints that were received by the Division during the three years ended December 31, 2004. We found that 39 of the 50 complaints were appropriately handled: the intake form was properly completed, the investigation was

adequately documented, and the investigation appeared to be reasonably thorough. However, we could not determine whether the remaining 11 complaints were appropriately handled, because an intake form was not completed for eight of the complaints and the investigation was not documented for three complaints.

The intake form is designed to ensure that the description of the complaint is as complete and accurate as possible. If a complaint is not recorded on an intake form, there is less assurance the complaint is fully and accurately described. If the complaint is not fully and accurately described, the investigation is less likely to be effective. If the investigation is not documented, there is less assurance an investigation was in fact performed, and if performed, was adequate.

The complaint intake and investigation process is not formally monitored to provide assurance complaints are handled in the required manner. For example, each step in the process could be tracked on an automated information system. When each step was completed, the date and the name of the individual who performed the step could be entered on the system. We recommend that a formal monitoring system be established for the handling of consumer complaints.

Compliance with Annual Certification Requirement

Dairy farms are inspected by private inspectors who are certified and overseen by the Division. The farms are to be inspected at least once every six months. At the time of our audit, there were a total of 117 certified inspectors statewide. The inspectors, who are employed by dairy processing plants, are required to meet with a Division inspector at least once every 90 days. The Division inspectors review the inspection reports prepared by the certified inspectors, and routinely visit dairy farms themselves to perform inspections and ensure that the sanitary requirements are in fact being met.

Certified inspectors must meet certain requirements to receive their initial certification. To maintain their certification, the inspectors must complete an annual refresher course provided by the Division. To determine whether private inspectors' compliance with this annual requirement was adequately monitored by the Division, we reviewed the procedures used by the Division to monitor compliance. We found that a list of the

inspectors' names is maintained in the Central Office, and the word "yes" is written next to each name when the annual certification requirement is met.

However, no documentation is maintained to show that the inspectors have in fact met the requirement. For example, attendance records are not maintained for the annual refresher course. In the absence of such documentation, there is less assurance the requirement has in fact been met for all the inspectors. We recommend that this documentation be maintained.

Recommendations

4. Develop a system for monitoring the handling of consumer complaints to ensure that complaints are properly documented and investigated.

(Department officials responded that they have already implemented a more formalized tracking procedure.)

5. Document certified inspectors' compliance with the annual certification requirement.

(Department officials responded that they have already implemented a more formal system for documenting the annual training requirements.)

MAJOR CONTRIBUTORS TO THIS REPORT

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August 15, 2005

Mr. Frank Houston
Audit Director
Office of the State Comptroller
110 State Street
Albany, NY 12235

Dear Mr. Houston:

Thank you for the opportunity to provide comments on your draft audit report of the Department's Dairy Inspection Program. We appreciate some of the revisions made in this draft based on our response to the preliminary report; however, there are still inaccuracies and misconceptions conveyed that do not present a true appraisal of the Program's effectiveness. We must express our disappointment with the report and the lack of understanding of dairy sanitation inspection practices and the impact of New York's program.

New York operates one of the most effective dairy sanitation inspection programs in the country and serves as a model for other states. The effectiveness of New York's dairy inspection program is supported by evaluations by the United States Food and Drug Administration (FDA) of our compliance with the Pasteurized Milk Ordinance (PMO). In the most recent evaluation, FDA states that "The Division is staffed with experienced, highly qualified, and dedicated individuals. The milk program is positioned to maintain superior supervision of the New York dairy industry." The report further states that all milk producers and processors that offer milk and milk products for interstate commerce are regulated and rated in accordance with the PMO and related IMS documents. The Program was further commended for its response to changes in aseptic processing and its flexibility in addressing crisis situations involving pathogens such as listeria and salmonella and drug residues from sulfamethazine.

While the FDA team of professional dairy sanitation experts evaluated and found the Department to operate an exemplary Dairy Inspection Program, little mention of the FDA report and its findings is made in the report.

*
Note
1

* See State Comptroller's Notes, page 41

The Department is widely recognized as a leader in developing new and innovative programs to improve the wholesomeness and safety of dairy products from the farm to the consumer while at the same time improving the economic viability of the dairy industry in New York State. A recent audit by your Office of our New York State Cattle Health Assurance Program (NYSCHAP) commended the Department for its efforts in developing the Program which is designed to improve herd health, productivity and profitability; assure food safety, public health and consumer confidence; and promote environmental stewardship.

Dairy products are arguably among the safest of all food products in the United States because of the effectiveness of milk sanitation programs like New York State's. Food borne illnesses attributed to dairy products account for less than one percent of all reported incidents. In the case of milk, there are numerous checks, tests and inspections from the farm to the store to help ensure consumers receive a safe, healthy and wholesome product. A producer sample is collected from every load of milk when picked up at a farm. Commingled milk delivered to a dairy plant is then tested before unloading at the processing plant. Any load that does not pass rigid quality standards or tests positive for antibiotics is discarded by the plant and not permitted to enter the human food chain. Over 99.5 percent of all milk delivered to plants passes inspection. Additional tests and checks are then conducted throughout processing to help ensure that the safest possible product leaves the plant. Finished products are also sampled and tested by the plant, our Dairy Product Specialists, and the Department's Food Laboratory.

*
Note
2

Inspections and Laboratory Tests

The statements on page 10 of the report that the Department does not take appropriate action when violations could pose a threat to public health are erroneous and unsubstantiated. Also inaccurate is the statement that unsafe foods are not confiscated to prevent sale to the public. These two statements exemplify our concern over the lack of understanding of dairy sanitation practices conveyed in the report. To categorize our enforcement program as lenient is a gross misstatement of fact completely unsubstantiated by any evidence. These statements and erroneous conclusions should be removed from the report. In no instances did the Division fail to follow established enforcement protocol. In fact, over \$10,000 in penalties were assessed against plants in your sample during the audit period.

*
Note
3

Our monitoring systems are not set up to facilitate a quick and cursory review of inspection/laboratory test histories by persons untrained in dairy sanitation. Division managers and field personnel do an exemplary job of monitoring compliance with sanitary requirements. Again, erroneous statements are being

* See State Comptroller's Notes, page 41

presented in the report without any substantiation or evidence of instances where the sanitary condition of a dairy plant was not properly monitored.

Milk Processing Plant Sanitation Inspections

As indicated in the report, the Division currently inspects 261 facilities that process milk, dairy products, frozen desserts, or otherwise handle milk or milk products.

The statement that the Division has no tracking system for the plant inspection process is incorrect. As explained during the audit, the Division uses a decentralized management approach, assigning responsibilities to the supervisors located in different regions throughout the State. Obviously this approach is effective since the audit recognizes that inspections are being conducted in a timely manner.

*
Note
4

Our experience shows that sanitary plant inspections have proven to be an effective mechanism for assessing a plant's compliance with sanitary requirements. Any violation found is evaluated for severity and a determination is made as to the best course of action to bring about compliance. Each facility has unique conditions and circumstances that warrant different approaches to bring about compliance. We have been most successful in gaining compliance by working closely with plant personnel and providing necessary education and training programs tailored to specific issues.

It needs to be emphasized that in the case of a category four rating--for violations that could result in a public health danger--immediate action is taken to stop the operation until the violation is corrected. In no cases did any of the inspection results cited in the report warrant taking more severe action than was actually taken.

We also believe the statistics and subsequent discussion on repeat violations are misleading because the findings overstate actual repeat violations.

*
Note
5

Plant inspection reports summarize violations of regulatory requirements by broad categories and numbered items on inspection score sheets. A narrative explanation is also included for each violation that provides a detailed description of the deficiency cited. These notes are a critical component of the inspection report used to assess the scope and severity of the sanitary conditions of the inspected facility and to determine a recommended course of corrective action. Accordingly, it is not possible to draw conclusions about the nature of any violation based on the summary category alone.

* See State Comptroller's Notes, page 41

Our review of the inspection reports cited indicates that in many cases the deficiency, while in the same summary category, was different than the one cited in the previous report. Our review also indicated that in many cases the previous violation had in fact been corrected and was indicated as such on the subsequent inspection report. The audit report also does not recognize the emphasis we place on the progress and improvements plants make in sanitary conditions from one inspection to the next, provided the conditions do not pose a threat to public health. In other cases, plants may have been cited during an inspection for several items within a particular category but then on the subsequent inspection were found to have corrected all but one of the violations. While such plants would still receive a written notice of the remaining violation, no further action would be taken as long as no public health threat existed and we were satisfied that the plant had demonstrated good progress in improving sanitary conditions.

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Note
5

There is a statement on page 13 that fines generally total \$200 per inspection. The average fine for your sampled plants was \$650.

*
Note
6

On pages 14, 15 and 16 there is misleading information regarding the PMO and the Division's enforcement actions. As explained to the auditors on numerous occasions, the PMO is not an enforceable federal or state regulation. Enforcement authority of New York dairy sanitation requirements is contained in Part 2 of the Department's Official Rules and Regulations. To the best of our knowledge, no plant nationwide has had its permit suspended or revoked when a single violation was repeated in two or more consecutive inspections. This is unfounded speculation on the auditors' part and reflects a lack of understanding of the role of the PMO. It is irresponsible to suggest that New York dairy standards are more lenient than the PMO, thus compromising public health.

*
Note
7

Statistics on the violations that have been called "repeat violations" differ from what was presented to us during the audit. Since no documentation was presented to us for review we are unable to comment on the accuracy except to refer to our previous discussion on what constitutes a true repeat violation. Also, the severity of the violation needs to be considered in determining appropriate enforcement action.

*
Note
5

All decisions regarding appropriate enforcement action are made by trained professionals recognized as experts in their field. New York has one of the most effective dairy inspection programs in the country as evidenced by the low rate of food borne illness attributable to dairy products. Plant deficiencies are being identified through inspection and corrected. When warranted, fines are assessed. There is no basis for your

* See State Comptroller's Notes, pages 41-42

conclusion that increased penalties will result in increased compliance.

Failed Laboratory Tests

It is difficult to comment on much of this section since this is new material to us that was not included in any preliminary findings. We also have not received any documentation in support of the findings to review for accuracy. We would appreciate receiving this documentation so we can comment on it prior to finalization of the final report.

*
Note
8

As with the previous section on plant inspections, this section on laboratory tests contains numerous inaccurate and misleading statements resulting in an unfair portrayal of the sampling part of our dairy sanitation program. Again, we must reiterate that the Division does not have a lenient enforcement program and that appropriate action was taken on all sample results. In instances where products were not confiscated or recalled, they did not pose a threat to public health.

*
Note
3

The State Food Laboratory is part of the Department of Agriculture and Markets, not the Department of Health. It may have been helpful for the auditors to have visited the Food Laboratory to observe first hand how dairy product samples are handled and tested.

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Note
9

Consumer Complaints

While all consumer complaints were investigated, we acknowledge that not all forms were filled out completely. We will make every effort to ensure all follow up actions are documented on the complaint form.

Annual Certification Requirements

All Certified Milk Inspectors are properly trained to conduct farm inspections and are certified by the Division on an annual basis. In addition to the annual CMI update session, Division Dairy Product Specialists routinely work with and review the Certified Milk Inspectors' inspection related activities on a quarterly basis. A quarterly newsletter is also sent to CMIs keeping them informed of developments that may impact their performance and responsibilities. The report cites a lack of comprehensive documentation for attendance at the annual update. Current practice is to require each CMI to sign in upon arrival. Division staff collects the update session sign-in sheets and

* See State Comptroller's Notes, pages 41-42

create a master list after which the sign-in sheets are discarded. We believe this meets our recordkeeping needs.

Recommendations

1.) Develop an automated system for tracking sanitary inspections at dairy processing plants. Use the system to ensure that inspections are performed on time, appropriate penalties are assessed for violations, penalties are increased when violations are repeated, and all fines are paid.

Response: Partially agree. The Department has initiated development of an automated system for tracking dairy plant inspections. Appropriate enforcement has and will continue to require individual attention and review by supervisory personnel.

2.) Develop an automated system for tracking laboratory tests for dairy processing plants. Use the system to ensure that tests are performed on time, corrective actions are taken when tests are failed, appropriate penalties are assessed for failures, penalties are increased when violations are repeated, and all fines are paid.

Response: Partially agree. The Department has initiated development of a system integrating the Food Lab testing system with other regulatory Divisions. This was initiated well before the audit. Appropriate enforcement has and will continue to require individual attention and review by supervisory personnel.

3.) Revise the Manual so that stronger actions are required from the Division in response to repeated violations and test failures. In particular, require that products be confiscated when samples fail laboratory tests.

Response: Disagree. The reference Manual is a field inspection manual. Enforcement is done in the Central Office to ensure uniformity and appropriate response based on the public health risks presented.

4.) Develop a system for monitoring the handling of consumer complaints to ensure that complaints are properly documented and investigated.

Response. Agree. The Division has already implemented a more formalized tracking procedure.

5.) Document certified inspectors' compliance with the annual certification requirement.

Response: Agree. The Division has already implemented a more formal system for documenting the annual training requirements.

If you have any questions or wish to discuss our response please let me know.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Francis", written in a cursive style.

William Francis
Director, Division of Milk Control
and Dairy Services

State Comptroller's Notes

1. The most recent evaluation of the Department's Dairy Inspection Program by the United States Food and Drug Administration, which we refer to in the Background section of the audit, covered the 2000 and 2001 calendar years. Our audit addressed the subsequent three-year period.
2. The Department states that over 99.5 % of all milk delivered to plants passes inspection. However, Department statistics also show that 6% of dairy products subsequently tested in the Department's Food Laboratory fail tests for bacterial contamination. Failure rates are even higher for other chemical content factors. If these statistics are accurate and representative, then it would follow that over 5% of the products become contaminated between the time they enter and exit the processing plants. This highlights the importance of employing a reliable and comprehensive plant inspection process.
3. Although the Department contends that it has taken appropriate actions on all sample results, we identified instances where the Department did not enforce its rules. One plant, for example, failed three out of five tests on three separate occasions, yet was only fined \$300, \$600, and \$300, respectively. In each case, the Department suspended the plant's operating permit, but immediately issued a temporary permit for it to continue processing. Furthermore, no food products were confiscated. The number of recurrent significant violations suggests that stronger actions are needed by the Division to curb the improper conditions.
4. The Division could not provide us with its tracking system for the plant inspections process. In addition, neither central nor regional office managers could provide us with summaries of expected or actual inspection completion dates. Instead, we had to review individual processing plant files to determine when inspections were completed. The development of an automated tracking system, which the Department has indicated it has initiated, would enable managers to monitor these activities and detect irregularities on a timely basis.
5. Based on Department officials' comments to the preliminary findings we presented to them during the audit, we revised our analysis to focus on individual occurrences, including multiple violations within the same category (i.e., what the Department describes as true repeat violations). Therefore, the number of repeat violations cited in this report differs from the number cited in our preliminary findings.
6. The statement regarding the fines per unsatisfactory inspection has been removed from the report.
7. Although the PMO is not the State's legal guideline, it is still valid and appropriate to recognize where the Department's procedures are inconsistent with these Federal

regulations. In fact, in its Introduction, the PMO states that it is specifically “recommended for legal adoption by States, Counties, and Municipalities, in order to encourage a greater uniformity and a higher level of excellence of milk sanitation practice in the United States.” Further, we state that the Department’s standards with respect to violations are more lenient than the PMO, not the standards in their entirety.

8. Because Department officials did not provide us with any information on their laboratory testing until after our exit conference, we did not issue formal preliminary findings on this material. However, we discussed our findings with Department officials and provided them with spreadsheets which summarized the results of our testing.
9. We revised the audit report to indicate that the Food Laboratory is part of the Department.