

An Evaluation

Food and Dairy Safety Program

*Department of Agriculture,
Trade and Consumer Protection*

2007-2008 Joint Legislative Audit Committee Members

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Janice Mueller
State Auditor

May 30, 2008

Senator Jim Sullivan and
Representative Suzanne Jeskewitz, Co-chairpersons
Joint Legislative Audit Committee
State Capitol
Madison, Wisconsin 53702

Dear Senator Sullivan and Representative Jeskewitz:

We have completed an evaluation of the food and dairy safety program administered by the Department of Agriculture, Trade and Consumer Protection (DATCP). This report focuses on the effectiveness of DATCP's regulatory activities and follows our January 2008 review of the program's funding. The program's expenditures totaled \$8.4 million in fiscal year (FY) 2006-07 and supported 97.6 full-time equivalent positions.

From FY 2004-05 through FY 2006-07, DATCP completed 79,743 routine inspections of food and dairy establishments. During this period, 98.7 percent of completed dairy inspections and 68.3 percent of completed food inspections were conducted when scheduled. DATCP has not developed formal inspection frequency standards for food establishments, which partially explains why a smaller percentage of food inspections were completed as scheduled.

While its approach to compliance appears effective in most cases, we found that DATCP is at times ineffective in gaining timely and continued compliance when follow-up is required after an inspection. In a review of 50 cases that suggested significant noncompliance with food and dairy safety regulations, we identified 13 in which DATCP did not take timely and sufficient enforcement action to ensure "permanent and continuous" compliance with food and dairy safety regulations.

In addition, we identified concerns with DATCP's oversight of contracts with local health departments that regulate retail food establishments, and with its documentation of food emergencies. We include several recommendations to improve program management and enhance food and dairy safety enforcement activities.

We appreciate the cooperation extended to us by DATCP in conducting this evaluation. A response from DATCP follows the appendices.

Respectfully submitted,

Janice Mueller
State Auditor

JM/PS/ss

Report Highlights ■

We found significant differences in the timeliness of food establishment inspections and dairy establishment inspections.

DATCP's compliance with food and dairy testing requirements is generally adequate.

DATCP did not take sufficient and timely enforcement action in some cases.

DATCP's oversight of local retail food regulatory activities needs improvement.

In responding to food emergencies, DATCP appears to have taken appropriate action.

The Department of Agriculture, Trade and Consumer Protection (DATCP) has primary responsibility for ensuring the safety of food and dairy products produced and sold by approximately 29,400 food and dairy establishments in Wisconsin, including dairy farms, dairy plants, food processors, food warehouses, grocery stores, delicatessens, and other retail food establishments. DATCP also regulates certain professionals involved in the production of food and dairy products and oversees contracts with local health departments that regulate approximately 5,000 retail food establishments. However, its responsibilities do not include restaurants, which are regulated by the Department of Health and Family Services (DHFS).

DATCP's food and dairy program is funded primarily with license fees paid by food and dairy establishments and professionals and with general purpose revenue (GPR). In fiscal year (FY) 2006-07, its expenditures totaled \$8.4 million and funded 97.6 full-time equivalent (FTE) staff positions. To determine the program's effectiveness, we reviewed DATCP's efforts to:

- conduct timely routine food and dairy safety inspections;
- collect and test food and dairy product samples and environmental samples from food preparation areas in order to monitor compliance with food safety procedures;

- ensure permanent and continuous compliance with state food and dairy safety regulations by all regulated entities;
- oversee local health departments' regulation of retail food establishments; and
- respond to food emergencies.

Inspection Timeliness

Approximately one-half of the food and dairy licenses issued by DATCP in FY 2006-07 were for dairy farms, and 84.2 percent of these farms had Grade A permits to produce milk that can be sold as fluid milk for human consumption. The remaining farms were classified as Grade B and produce milk for use in manufactured products, such as cheese.

To help ensure the safety of food and dairy products, DATCP regularly inspects food and dairy establishments to determine compliance with food and dairy safety standards. Inspection frequency is based on state law or informal DATCP guidelines and ranges from every three months to every two years, based on establishment type and the potential risk of foodborne illness.

From FY 2004-05 through FY 2006-07, DATCP completed 66,874 inspections of dairy establishments and 12,869 food inspections. As shown in Table 1, we found that 98.7 percent of the dairy inspections were conducted when scheduled, compared to 68.3 percent of food inspections. Of the 4,929 inspections completed after they were scheduled, 29.3 percent were completed within 30 days, but 8.3 percent were overdue by more than one year.

Table 1

Timeliness of Completed Routine Food and Dairy Inspections
 FY 2004-05 through FY 2006-07

	Dairy		Food		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
Completed by Date Scheduled	66,025	98.7%	8,789	68.3%	74,814	93.8%
Completed after Date Scheduled	849	1.3	4,080	31.7	4,929	6.2
Total	66,874	100.0%	12,869	100.0%	79,743	100.0%

DATCP inspections were more timely for establishments whose inspection frequency is specified in state law. For example, inspections of dairy farms and Grade A dairy plants almost always adhered to the frequencies specified in state law. State law does not specify inspection frequencies for Grade B dairy plants or retail food establishments. We found that 30.1 percent of inspections of Grade B dairy plants and 31.7 percent of food establishment inspections were not completed when scheduled.

Sampling and Testing

DATCP routinely collects and analyzes samples of products from all Grade A dairy plants to fulfill mandatory national and state testing requirements intended to ensure that the milk has been pasteurized and is free of drug residue and harmful bacteria.

In most instances, DATCP’s sampling efforts met the requirements. Only 1.2 percent of the results of 29,454 tests conducted from FY 2002-03 through FY 2006-07 exceeded specified limits for temperature or bacteria. However, in 26 of the 54 instances in which test results showed high levels of bacteria in sampled products, DATCP responded an average of 22 days past the required time frame.

In addition, DATCP tested 12,459 samples of food and food preparation environments for the presence of pathogens that can cause foodborne illnesses. The collection and testing of these samples, which are taken from food processors, dairy plants, and retail food establishments, is not required by state law but is guided by a plan developed annually by DATCP.

We found that while the number of environmental samples collected increased 40.0 percent from FY 2002-03 through FY 2006-07, DATCP collected substantially fewer environmental samples than it had planned in each of these years. This is a concern because DATCP is performing fewer tests on food and is increasing its reliance on environmental sampling to monitor food safety.

Enforcement Practices

DATCP seeks voluntary compliance from all regulated entities, and this approach appears to be effective for the vast majority of regulated establishments. In 94.4 percent of routine inspections, no need for follow-up regulatory action was identified. When additional action is needed, DATCP's policy is to use progressively more stringent enforcement action to gain "permanent and continuous" compliance with food and dairy regulations.

To evaluate the effectiveness of DATCP's compliance and enforcement efforts in instances requiring additional action, we reviewed 50 cases that suggested significant noncompliance with food and dairy safety regulations. We believe DATCP did not take timely and sufficient enforcement action in 13 of these cases.

For example, in September 2004 DATCP placed a Grade A dairy farm under a conditional license, but only after having identified 130 violations during 29 inspections over a period of more than seven years. DATCP temporarily suspended the farm's conditional license for four days in May 2006 but issued a regular license four months later, even though the farm had not achieved permanent and continuous compliance with dairy regulations.

DATCP's difficulties in effectively gaining compliance with establishments that do not willingly cooperate are longstanding and were noted in our December 1983 and November 1985 audits of its food and dairy safety program.

Local Oversight

DATCP has entered into agreements with 34 local health departments to regulate 51.7 percent of grocery stores, delicatessens, and other retail food establishments in Wisconsin. The local health departments license and inspect retail food establishments, establish and collect fees, and annually pay DATCP 10.0 percent of the license fee revenue it would otherwise have received for licensing the retail food establishments. To ensure consistency in conducting inspections, DATCP provides regular training and support for local health departments that appears to be sufficient and relevant.

Administrative rules require DATCP to annually review and evaluate the retail food safety efforts of each participating local health department. However, since 2004 DATCP has not conducted any of the required local evaluations. Instead, for the past two years it has relied on self-reporting by local health departments. This strategy has been ineffective, largely because only 21 of the 34 local health departments submitted data to DATCP for FY 2006-07, and not all of the reports submitted contained complete information.

Food Emergencies

DATCP is the lead state agency responsible for responding to foodborne illnesses, disease outbreaks, and other emergencies in which the food supply is threatened. It has developed response plans based on the type and scale of food emergency. DATCP identified 41 food emergencies from FY 2002-03 through FY 2006-07. Six of these involved human illnesses and affected between 1 and 61 people.

We reviewed the files for the 41 food emergencies and found that DATCP took appropriate action in responding to 40 cases. However, a lack of documentation prevented us from determining whether appropriate action had been taken in response to one case involving listeria, a foodborne pathogen, and DATCP was unable to provide additional information on this incident.

In addition, we found that staff were not following all procedures in DATCP's food emergency response manual, including keeping a log of events and contacts during a food emergency, critiquing the process, and preparing a written report after each case is closed. For example, only 1 of the 41 food emergency case files contained a final written report.

Recommendations

We include recommendations for DATCP to report to the Joint Legislative Audit Committee by January 5, 2009, on:

- ☑ its efforts to develop formal inspection frequency standards for Grade B dairy plants and food establishments and to measure compliance of all regulated establishments with inspection frequency standards (*p. 22*);
- ☑ its efforts to increase the percentage of planned environmental samples that are collected and tested annually (*p. 31*);
- ☑ its efforts to enhance the timeliness and effectiveness of food and dairy enforcement actions, including requiring establishments with conditional licenses to achieve full regulatory compliance before a regular license is issued (*p. 40*);
- ☑ its plans to improve the review of local health departments' retail food safety activities (*p. 46*); and
- ☑ its efforts to ensure compliance with internal food emergency safety response procedures (*p. 52*).

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Introduction ■

Outbreaks of foodborne illness have raised concerns about the safety of the nation's food and dairy products.

Recent national outbreaks of foodborne illnesses have raised concerns about the safety of the nation's food and dairy products. The contaminated spinach outbreak in fall 2006 particularly affected the residents of Wisconsin. Over the past ten years, the number of reported instances of foodborne illness in Wisconsin has ranged from 276 to 1,292 instances per year, including 748 instances in 2007 that resulted in 11 hospitalizations. Public health officials believe the actual number of foodborne illnesses is likely much higher because individuals do not typically report mild cases.

In conducting this evaluation, we analyzed the timeliness of food and dairy inspections, the compliance of DATCP's sampling and testing program with national and state requirements, and the adequacy of DATCP's enforcement activities, oversight of local regulatory efforts, and response to food emergencies. In addition, we interviewed DATCP staff; food and dairy interest groups; and regulatory staff in the surrounding midwestern states of Minnesota, Michigan, Illinois, and Iowa, as well as staff in California and New York, which are both large dairy producers. DATCP also administers a separate meat inspection program that was not reviewed as part of this evaluation. The regulation of restaurants was not included in this evaluation because these are regulated by the Department of Health and Family Services (DHFS).

It has been more than 20 years since we last reviewed DATCP's food and dairy safety program. In 1983 (Report 83-37), we found that food establishments were seldom penalized for serious violations of state regulations except after a long history of serious code

violations, and in 1985 (report 85-29) we identified the need for additional procedures to ensure that all food and dairy establishments were inspected on a timely basis and that regulations were consistently applied and enforced.

Approximately one-half of all FY 2006-07 licenses were for dairy farms.

As shown in Table 2, approximately one-half of the food and dairy licenses issued by DATCP in FY 2006-07 were for dairy farms. Although the number of food licenses increased by 318 from FY 2004-05 through FY 2006-07, the number of dairy licenses declined by 4.9 percent. Of the 14,272 licensed dairy farms in FY 2006-07, 84.2 percent had Grade A permits to produce milk that can be sold as fluid milk for human consumption. The remaining farms were classified as Grade B and produce milk to be used in manufactured products such as cheese.

Table 2
Food and Dairy Licenses Issued by DATCP

License Type	FY 2004-05	FY 2006-07	Percentage Change
Food			
Retail Food	4,399	4,625	5.1%
Food Processors	1,249	1,270	1.7
Food Warehouses	816	887	8.7
Subtotal Food	6,464	6,782	4.9
Dairy			
Dairy Plants	371	368	(0.8)
Dairy Farms ¹	15,450	14,272	(7.6)
Other Dairy ²	7,941	7,962	0.3
Subtotal Dairy	23,762	22,602	(4.9)
Total	30,226	29,384	(2.8)

¹ Represents the number of active dairy farm licenses, rather than the number of licenses issued, because dairy farm licenses do not expire.

² Includes bulk milk tankers, bulk milk weighers and samplers, and dairy professionals, such as bulk milk tank operators and cheese and butter graders.

Regulation of food and dairy products in Wisconsin is heavily influenced by two model ordinances.

Regulation of food and dairy products in Wisconsin is heavily influenced by the Pasteurized Milk Ordinance and the national Retail Food Code, two model ordinances that were created and are periodically updated by the states and the federal government, with input from the food and dairy industries, dairy laboratories, and academic researchers. The Pasteurized Milk Ordinance governs the processing and production of Grade A milk and dairy products. All states meet its requirements, which allow for the shipment of Grade A dairy products across state lines. The national Retail Food Code describes safety procedures for cooking and cooling food, employee health requirements, and sanitizing techniques for retail food establishments and has been adopted by all but four states: California, Kentucky, Maryland, and North Carolina. Most provisions in these ordinances have been incorporated directly into Wisconsin law through statutes and administrative rules.

While state compliance with these two ordinances is voluntary, adherence promotes consistency across regulatory jurisdictions nationwide. The United States Food and Drug Administration (FDA) performs some monitoring of states' compliance with the Pasteurized Milk Ordinance by periodically reviewing each state's program. In addition, it provides periodic training on both ordinances' standards and best practices for implementing their provisions.

Staffing and Expenditures

Approximately one-half of DATCP's 97.6 FTE staff positions are for food and dairy safety inspectors.

As shown in Table 3, approximately one-half of DATCP's positions in FY 2006-07 were for inspectors, who are food scientists and either registered sanitarians or new employees in the process of becoming registered. Staffing levels increased from 94.5 FTE positions in FY 2002-03 after staff responsible for evaluating and certifying Grade A dairy farms and dairy plants based on national standards were transferred from DHFS to DATCP in FY 2003-04.

Table 3

Food and Dairy Safety Staffing¹
FY 2006-07

Classification	FTE Positions	Percentage
Program Staff		
Inspectors	48.1	49.3%
Supervisors	6.0	6.2
Other ²	25.0	25.6
Subtotal	79.1	81.1
Support Staff	13.5	13.8
Administrative Staff	5.0	5.1
Total	97.6	100.0%

¹ Includes both filled and vacant positions.

² Includes food and dairy specialists, a regulatory compliance investigator, laboratory evaluation officers, milk rating officers, and multiple product graders.

Inspectors, who typically work out of their homes, visit food and dairy establishments, collect samples of food and dairy products for testing, and respond when needed to food emergencies. In FY 2006-07, they participated in an average of nine training courses focusing on food safety and administrative issues.

As shown in Table 4, FY 2006-07 program expenditures totaled \$8.4 million, which is an increase of 16.8 percent since FY 2002-03. Almost three-fourths of the FY 2006-07 expenditures were for salaries and fringe benefits.

Table 4

Food and Dairy Safety Program Expenditures

Funding Source	FY 2002-03		FY 2006-07	
	Amount	Percentage	Amount	Percentage
Program Revenue	\$3,643,800 ¹	50.8%	\$4,601,100	54.9%
GPR	3,189,800	44.4	3,484,800	41.6
Federal Revenue	341,500	4.8	293,500	3.5
Total	\$7,175,100	100.0%	\$8,379,400	100.0%

¹ Includes a lapse of \$431,400 to the General Fund.

Food and dairy fees have funded an increasing share of program expenditures over time.

The program's largest funding source is revenue from license fees paid by regulated entities, which funded 54.9 percent of expenditures in FY 2006-07. During the five-year period shown, the amount of GPR funding increased, but the percentage of expenditures funded by GPR declined from 44.4 percent to 41.6 percent. Over this period, fees were increased once, in 2006.

Federal funds reimburse DATCP for the activities conducted under contracts to inspect federally regulated food processing plants and egg producers, packers, and hatcheries, and for a federal study of foodborne pathogens on produce and pesticide residues in food.

Our analysis of fees and staffing, including comparisons with other states and local governments, was included in a letter report on food and dairy safety program funding that we issued in January 2008. DATCP submitted proposed administrative rules to the Legislature in December 2007. At the request of the Assembly Committee on Agriculture, DATCP submitted modified rules in February 2008, which were approved by the Legislature in March 2008. These rules increase 65 of the 67 food and dairy establishment and professional fees by approximately 23 percent beginning July 1, 2008. The rules also increase the Grade A milk procurement fee, which is a monthly fee paid by dairy plants based on the amount of milk they receive from dairy farms, by 9.2 percent.

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Assessing Compliance ■

To help ensure the safety of food and dairy products, DATCP:

- inspects food and dairy establishments for compliance with food and dairy safety and licensing requirements; and
- tests for the presence of pathogens in food and dairy products and on food preparation surface areas.

We examined the frequency of food and dairy inspections in Wisconsin and other states, DATCP's timeliness in conducting routine inspections, the frequency of re-inspections that address food and dairy safety violations, and sampling and testing activities.

Safety Inspections

DATCP conducts two primary types of inspections: routine inspections and re-inspections.

DATCP conducts two primary types of inspections: routine inspections that are ongoing and intended to determine compliance with food and dairy safety regulations, and re-inspections that are generally conducted to address violations found during a prior inspection. Inspections are mostly unannounced, although a time frame for re-inspection is generally provided. Inspections include a physical examination of the establishment and equipment and a review of pertinent records. They are usually completed within an hour for a small dairy farm, and in up to three days for a large dairy plant.

Routine Inspection Frequency

Routine inspections for food and dairy establishments are scheduled to occur every 3 to 24 months.

As shown in Table 5, the frequency of routine inspections at food and dairy establishments ranges from every three months to every two years, depending on establishment type and food safety risk. “Potentially hazardous” establishments process, sell, or store foods that must be heated or cooled in order to be safe to consume, such as delicatessen meats and cheeses. Inspection frequency is specified by statute for Grade B dairy farms and established by administrative rule for Grade A dairy farms and Grade A dairy plants. For other regulated entities—including Grade B dairy plants, retail food establishments, food processors, and food warehouses—DATCP has established informal guidelines, which are based on food safety risk factors. The guidelines are programmed into its electronic licensing database, which includes food and dairy license information, the date and type of inspection conducted at each licensed establishment, and general inspection results.

Table 5

Scheduled Frequency of DATCP Inspections

	Establishment Type	Basis
3 to 12 months	Grade A Dairy Farms	Administrative Rules
3 months	Grade A Dairy Plants	Administrative Rules
6 months	Grade B Dairy Plants	Informal Guidelines
8 months	Food Processing Establishments—Potentially Hazardous ¹	Informal Guidelines
	Retail Food Establishments—Potentially Hazardous ¹	Informal Guidelines
12 months	Food Processing Establishments—Not Potentially Hazardous	Informal Guidelines
	Food Warehouses—Potentially Hazardous ¹	Informal Guidelines
	Retail Food Establishments—Not Potentially Hazardous	Informal Guidelines
24 months	Grade B Dairy Farms	Statutes
	Retail Food Establishments—No Processing Conducted	Informal Guidelines
	Food Warehouses—Not Potentially Hazardous	Informal Guidelines

¹ “Potentially hazardous” establishments process, sell, or store foods that must be heated or cooled in order to be safe to consume.

Wisconsin has adopted a performance-based farm inspection system for Grade A dairy farms.

Wisconsin has adopted a performance-based farm inspection system for Grade A dairy farms, as allowed under the Pasteurized Milk Ordinance. Under this system, these farms are inspected between one and four times per year, based on the results of prior inspections and milk quality tests conducted during the past 12 months. Grade A dairy farms with favorable outcomes are inspected only once per year, while those demonstrating compliance concerns are inspected either every three months, every four months, or every six months.

As shown in Table 6, the majority of Grade A dairy farms are scheduled to be inspected once every six months, while 30.8 percent are scheduled to be inspected every 12 months and 3.6 percent are scheduled to be inspected every 3 months.

Table 6
Scheduled Frequency of Wisconsin Grade A Dairy Farm Inspections
 As of June 30, 2007

Inspection Frequency	Number of Farms	Percentage
Once Every 3 Months	434	3.6%
Once Every 4 Months	1,150	9.5
Once Every 6 Months	6,785	56.1
Once Every 12 Months	3,728	30.8
Total	12,097	100.0%

Except for Grade B dairy farms, Wisconsin’s dairy establishment inspection frequency is comparable to that of most other states.

We reviewed inspection frequencies for dairy farms and plants in surrounding midwestern states and in California and New York, which are both large dairy producers. As shown in Table 7, Wisconsin’s inspection frequencies for Grade A dairy farms and Grade A and Grade B dairy plants are comparable to most other states’. As noted, DATCP is statutorily required to inspect Grade B dairy farms only once every 24 months. California, which produces more milk than any other state, requires the most frequent inspection of Grade A dairy farms. However, California has approximately 2,000 dairy farms with an average herd size of 908 cows, compared to Wisconsin’s 14,300 dairy farms with an average herd size of 85 cows.

Table 7

States' Dairy Establishment Inspection Frequencies

	Grade A Dairy Farms	Grade B Dairy Farms	Grade A Dairy Plants	Grade B Dairy Plants
California	2 Months	12 Months	Monthly	1 to 3 Months
Illinois	6 Months	12 Months	3 Months	6 Months
Iowa	6 Months	6 Months	3 Months	6 Months
Michigan	6 Months	12 Months	3 Months	6 Months
Minnesota	6 Months	12 Months	3 Months	6 Months
New York	6 Months	6 Months	3 Months	3 Months
Wisconsin	3 to 12 Months	24 Months	3 Months	6 Months

As shown in Table 8, there is more variation among states in inspection frequency for food establishments. Like Wisconsin, the states we contacted have generally developed systems based on the potential risk of a foodborne illness: the greater the risk, the more frequent the inspections. For food inspection, Wisconsin falls in the middle of inspection frequencies for each of the three risk categories.

Table 8

States' Food Establishment Inspection Frequencies

	High-Risk	Moderate-Risk	Low-Risk
California ¹	6 to 12 Months	12 to 18 Months	24 to 36 Months
Illinois ¹	12 Months	12 Months	At Least Every 5 Years
Iowa	12 Months	12 Months	12 Months
Michigan	6 Months	18 Months	24 Months
Minnesota	12 Months	18 Months	24 Months
New York	4 Months	6 Months	12 Months
Wisconsin	8 Months	12 Months	24 Months

¹ Represents only food processors; retail food inspection frequencies are determined by local governments.

As noted, inspection frequencies for Wisconsin dairy farms and Grade A dairy plants are codified in either statutes or administrative rule. Similarly, five of the six states we contacted have codified in state law the inspection frequency requirements for Grade A dairy farms and dairy plants, and four states have done so for Grade B dairy farms.

For both Grade B dairy plants and food establishments, codified inspection frequencies were less common and less consistent across the states we reviewed. California, Michigan, and Minnesota statutes specify inspection frequencies for Grade B dairy plants, but only Minnesota has statutory inspection frequency requirements for food establishments. The remaining states reported that they have either written internal policies or unwritten, informal guidelines, as shown in Table 9.

Table 9

Source of Inspection Frequency Requirements

State	Grade A Dairy Farms	Grade B Dairy Farms	Grade A Dairy Plants	Grade B Dairy Plants	Food Establishments ¹
California	Administrative Rule	Administrative Rule	Statutes	Statutes	Informal Guidelines
Illinois	Statutes	Administrative Rule	Statutes	Informal Guidelines	Informal Guidelines
Iowa	Statutes	Informal Guidelines	Statutes	Informal Guidelines	Informal Guidelines
Michigan	Statutes	Statutes	Statutes	Statutes	Written Internal Policy
Minnesota	Statutes	Statutes	Statutes	Statutes	Statutes
New York	Written Internal Policy	Written Internal Policy	Written Internal Policy	Written Internal Policy	Written Internal Policy
Wisconsin	Administrative Rule	Statutes	Administrative Rule	Informal Guidelines	Informal Guidelines

¹ Includes retail food establishments, food processors, and food warehouses.

Timeliness of Routine Inspections

We reviewed inspection data from DATCP's electronic licensing database for FY 2004-05 through FY 2006-07 to determine the extent to which routine inspections occurred as scheduled. DATCP's electronic licensing system automatically determines when the next inspection is scheduled to occur, based on:

- frequencies specified in state law for Grade A dairy farms, Grade A dairy plants, and Grade B dairy farms; and
- DATCP’s informal guidelines for Grade B dairy plants, retail food establishments, food processors, and food warehouses.

Inspections of dairy establishments were much more likely to be completed on time than inspections of food establishments.

We found that inspections of dairy establishments were much more likely to be completed on time than inspections of food establishments. As shown in Table 10, 98.7 percent of completed dairy inspections from FY 2004-05 through FY 2006-07 were completed by the date scheduled, compared to only 68.3 percent of food inspections.

Table 10

Timeliness of Completed Routine Food and Dairy Inspections¹
FY 2004-05 through FY 2006-07

	Dairy		Food		Total	Percentage
	Number	Percentage	Number	Percentage		
Completed by Date Scheduled	66,025	98.7%	8,789	68.3%	74,814	93.8%
Completed after Date Scheduled	849	1.3	4,080	31.7	4,929	6.2
Total	66,874	100.0%	12,869	100.0%	79,743	100.0%

¹ Excludes 2,555 scheduled inspections for which timeliness could not readily be determined.

Of the 4,929 inspections that were completed after the date scheduled, 8.3 percent were more than one year overdue.

As shown in Table 11, of the 4,929 overdue inspections that were completed, 18.8 percent were between six months and one year overdue and 8.3 percent were more than one year overdue. Overall, dairy inspections were more timely than food inspections: 42.6 percent of overdue dairy inspections were completed within 30 days, compared to 26.6 percent of overdue food inspections.

Table 11

Completed Food and Dairy Inspections That Were Overdue¹
FY 2004-05 through FY 2006-07

Days Overdue	Dairy		Food		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
1 to 30	362	42.6%	1,085	26.6%	1,447	29.3%
31 to 90	258	30.4	1,187	29.1	1,445	29.3
91 to 180	108	12.7	596	14.6	704	14.3
181 to 365	104	12.3	822	20.1	926	18.8
More than 365	17	2.0	390	9.6	407	8.3
Total	849	100.0%	4,080	100.0%	4,929	100.0%

¹ Excludes 2,555 scheduled inspections for which timeliness could not readily be determined.

The most consistent factor associated with the differences in inspection timeliness between food and dairy establishments appears to be whether inspection frequency is specified in state law. For example, while inspections of Grade A dairy farms, Grade A dairy plants, and Grade B dairy farms were almost always timely and met inspection frequencies specified in statutes and administrative rules, inspections of Grade B dairy plants, for which inspection frequency is not specified in state law, were not completed when scheduled 30.1 percent of the time. In addition, as noted, inspections of food establishments, whose frequency is also not specified in state law, were not conducted when scheduled 31.7 percent of the time.

This finding is consistent with comments made by DATCP staff, who indicated that inspections required in state law are typically conducted first, while other types of inspections are conducted based on food safety risk and as time and resources allow. As such, inspections of dairy farms are timely, even though DATCP staff have indicated that most retail food establishments and food processors have a higher food safety risk.

As was shown in Table 9, three of the states we contacted—Michigan, Minnesota, and New York—have developed written standards for the inspection frequency of all food and dairy establishments they regulate. The establishment of such standards is a simple management practice that may help to ensure the effectiveness of food and dairy safety programs. The development of formal standards could assist DATCP in improving inspection

timeliness of Grade B dairy plants and all types of food establishments, as well as provide its managers with an important tool for assessing the adequacy of DATCP's regulatory oversight.

Recommendation

We recommend the Department of Agriculture, Trade and Consumer Protection:

- *develop formal standards for the inspection frequencies of Grade B dairy plants and all of the food establishments it licenses, including food processors, retail food establishments, and food warehouses;*
- *regularly measure compliance with these standards, as well as those established by state law for dairy farms and dairy plants; and*
- *report to the Joint Legislative Audit Committee by January 5, 2009, on the standards it has developed, how it will measure compliance with the standards, and whether it plans to propose any of the standards as statutes or administrative rules.*

Re-Inspections

Two types of re-inspection can be conducted when an inspector determines that additional action is needed to address violations: a follow-up inspection, during which the inspector returns to verify that a specific violation has been corrected, and a complete re-inspection, which is scheduled when an inspector finds a general lack of compliance with adequate food and dairy safety procedures at an establishment that may have had multiple violations. DATCP policy states that re-inspections are to occur within a specified time frame after the original inspection, usually within one month. DATCP may charge a fee for re-inspections, as specified in administrative rule. Fees are typically charged when a re-inspection is conducted to address a significant number of violations or to address violations that were found during multiple inspections.

Routine inspections of Grade B dairy farms were most likely to result in re-inspection.

We found that 94.4 percent of the routine inspections completed between FY 2004-05 and FY 2006-07 did not require additional action. Grade B dairy farms were most likely to require re-inspection. Following routine inspections, 17.7 percent of Grade B dairy farms

required re-inspection, compared to between 1.2 percent and 5.3 percent for other types of food or dairy establishments.

Food establishments are less likely to achieve compliance upon re-inspection than dairy establishments.

As shown in Table 12, 8.4 percent of the 4,330 re-inspections of food and dairy establishments conducted from FY 2004-05 through FY 2006-07 required some type of additional regulatory action. Re-inspections of Grade B dairy farms and food warehouses were most likely to result in additional regulatory action. However, food establishments as a group were less likely to achieve compliance upon re-inspection: 14.2 percent of food establishment re-inspections required additional action, compared to 7.5 percent of dairy establishment re-inspections.

Table 12

Results of Re-Inspections¹
FY 2004-05 through FY 2006-07

	Re-Inspections Conducted	Re-Inspections Requiring Additional Action			Percentage of Re-Inspections Conducted
		Another Re-Inspection Required	Referred for Other Enforcement Action	Total	
Dairy					
Grade A Dairy Farms	2,886 ²	107	0	107	3.7%
Grade B Dairy Farms	767 ³	168	0	168	21.9
Grade A Dairy Plants	30	0	1	1	3.3
Grade B Dairy Plants	63	2	2	4	6.3
Dairy Total	3,746	277	3	280	7.5
Food					
Food Processors	88	11	0	11	12.5
Food Warehouses	17	4	0	4	23.5
Retail Food	479	64	4	68	14.2
Food Total	584	79	4	83	14.2
Total	4,330	356	7	363	8.4

¹ Includes only those establishments in business as of June 30, 2007.

² Includes 45 re-inspections for which we were unable to determine if additional action was required.

³ Includes 29 re-inspections for which we were unable to determine if additional action was required.

Sampling and Testing Activities

DATCP collects and analyzes samples from dairy plants, food processors, and retail food establishments.

DATCP routinely collects and analyzes samples of products from all Grade A dairy plants to fulfill mandatory testing requirements, and it collects and analyzes samples from food processors, dairy plants, and retail food establishments for additional food safety testing. In addition, it participates in a federal study by collecting samples of food products to gather data on foodborne pathogens on produce and pesticide residues in food.

Mandatory Testing Requirements

In four separate months in every six-month period, DATCP is required by administrative rule to collect a sample of raw, or unpasteurized, milk and a sample of each pasteurized product produced at each Grade A dairy plant in Wisconsin. We reviewed samples collected at each of the 35 Grade A dairy plants operating in Wisconsin at any time from FY 2002-03 through FY 2006-07, the results of tests conducted on the samples, and DATCP’s response when problems were identified.

DATCP’s sampling responsibilities have generally been conducted as required.

In most instances, DATCP’s sampling efforts met the requirements. However, as shown in Table 13, we found at least one instance of products in 13 of the 35 plants not being sampled as required, either because they were not available at the time of the visit and follow-up samples were never collected, or because a sample was rejected by the laboratory and a new sample was not collected.

Table 13

Sampling Frequency in Grade A Dairy Plants¹

	Grade A Dairy Plants Not Sampled as Required	Total Grade A Dairy Plants	Percentage of Grade A Dairy Plants Not Sampled As Required
2002-03	7	29	24.1%
2003-04	7	33	21.2
2004-05	4	30	13.3
2005-06	5	32	15.6
2006-07	6	33	18.2
All Years	13	35	37.1

¹ We could not determine if five plants were sampled adequately.

The Pasteurized Milk Ordinance requires:

- all dairy samples to arrive at DATCP's food and dairy laboratory within a strictly defined temperature range so that testing will be accurate; and
- pasteurized products to be tested for the presence of phosphatase, an enzyme that should be destroyed along with harmful microorganisms during pasteurization and whose presence is an indication that the pasteurization process may not be working properly. A positive result for phosphatase should result in immediate action to determine the cause.

In addition, both the Pasteurized Milk Ordinance and Wisconsin administrative rules require:

- all raw and most pasteurized dairy samples to be tested for antibiotic drug residues, which are prohibited and whose presence should result in immediate action to determine the cause;
- pasteurized products to be tested for coliform, a type of bacteria that is destroyed during pasteurization and whose presence in pasteurized products is an indicator of unsanitary processing conditions; and
- all samples to be tested for the presence of certain other bacteria, which must not exceed specified levels for each product.

Overall, the results of only 1.2 percent of mandated tests on dairy products exceeded specified limits.

A total of 16,797 samples were collected from the 35 Grade A dairy plants from FY 2002-03 through FY 2006-07. Table 14 identifies the five types of required tests, the number of tests performed, and the number of test results that exceeded established limits. Overall, only 1.2 percent of test results exceeded these limits. However, we found that from FY 2002-03 through FY 2006-07, 28 samples were outside of the acceptable temperature range, including 1 on which DATCP performed additional testing although it should have been rejected. In addition, we found three samples for which the required temperature reading had not been recorded. To ensure the validity of the test results, samples collected for testing must be between 0 and 4.4 degrees Celsius on arrival, or up to 7.0 degrees Celsius if they arrive within 3 hours of collection.

Table 14

Testing of Grade A Dairy Plants
 FY 2002-03 through FY 2006-07

Test Type	Tests Performed	Test Results Exceeding Limits	Percentage of Test Results Exceeding Limits
Temperature	2,788	28	1.0%
Phosphatase	6,006	7	0.1
Drug Residue	5,805	0	0.0
Coliform	8,119	124	1.5
Bacterial Count	6,736	185	2.7
Total	29,454	344	1.2

In seven cases, DATCP’s tests showed the presence of phosphatase. In four of these cases, new samples were collected on a timely basis, typically within one week. However, in the other three cases, new samples were not collected for an average of 40 days from the initial test date. Furthermore, the results of 124 coliform tests from 22 dairy plants and 185 bacterial count tests from 23 dairy plants exceeded limits defined in administrative rules and the Pasteurized Milk Ordinance. When allowable limits are exceeded in two of the most recent four tests, DATCP is required by the Pasteurized Milk Ordinance to issue a warning letter to the dairy plant and to collect a follow-up sample within 21 days. When allowable limits are exceeded in three of the most recent five tests, DATCP is required by the ordinance to suspend the plant’s Grade A permit or degrade the product so that it can no longer be sold as Grade A.

DATCP did not consistently respond in a timely manner when test results showed high levels of bacteria in Grade A dairy plants.

We identified 54 cases in which DATCP was required to issue warning letters and collect follow-up samples within 21 days. However, DATCP’s response exceeded the 21-day limit in 26 cases, as shown in Table 15, and averaged 43 days. DATCP issued warning letters in only 24 cases. Moreover, the frequency of violations required DATCP to suspend a Grade A permit or degrade a dairy product in 11 cases, but these required actions appear to have been taken in only 4 cases.

Table 15

Timeliness of Response to Unallowable Bacteria Levels in Grade A Dairy Plants
FY 2002-03 through FY 2006-07

DATCP Action	Cases	Percentage
Follow-up Sample Collected		
Within 21-Day Required Limit	28	51.9%
More than 21 Days	26	48.1
Total	54	100.0%
Warning Letters Sent		
Yes	24	44.4
No	30	55.6
Total	54	100.0%
Product Degraded or License Suspended		
Yes	4	36.4
No	7	63.6
Total	11	100.0%

Non-Mandated Testing Activities

As shown in Table 16, DATCP and some local health departments collected 12,459 food samples from retail food establishments, food processors, or dairy plants from FY 2002-03 through FY 2006-07. Collected samples included dairy products, food, and environmental samples, which test food preparation areas for the presence of pathogens such as listeria and salmonella, which could cause a foodborne illness. The samples collected from dairy plants are in addition to the mandated sampling discussed previously.

Table 16

Collection of Non-Mandated Food and Dairy Samples
 FY 2002-03 through FY 2006-07

	Responsible Agency	Samples Analyzed	Percentage
Retail Food and Food Processors	DATCP	6,874	55.2%
Dairy Plants	DATCP	2,842	22.8
Retail Food	Local Health Departments	2,743	22.0
Total		12,459	100.0%

There are no requirements in state law for the collection and testing of food products or production environments.

There are no statutory or administrative rule requirements for the collection and testing of food products or production environments, which can include equipment, utensils, countertops, sinks, and bowls that unpackaged food may have contact with. DATCP develops an annual plan outlining the number and types of products to be tested and the environmental samples to be collected from the processing environment in that year, as well as the types and locations of establishments from which they are to be collected. The annual plan does not identify specific establishments from which samples are to be collected; establishments are selected by the inspector collecting the samples. DATCP indicated that all sampling visits are unannounced.

The annual plan identifies foods with the greatest risk of carrying a pathogen, such as delicatessen meats and salads, which are to be collected and tested for bacteria and other pathogens. Beginning in FY 2006-07, most products tested for foodborne pathogens have been collected from food processors. Previously, food products in retail food establishments were also tested for pathogens, but because of the time lag between when samples were collected and when the test results were available, any food containing a pathogen would have likely already been sold and consumed. Instead, DATCP increased the number of environmental samples it collects. DATCP and local health departments continue to collect food samples from retail food establishments for other types of tests. For example:

- ground beef is tested to identify the fat content and species from which the meat came;
- foods such as salsa, pickled vegetables, and pickled eggs are tested for acidity levels to determine whether these levels are adequate to prevent the growth of foodborne pathogens; and

- dairy products are tested for moisture and fat content to determine compliance with product quality standards.

The number of environmental samples collected increased 40.0 percent from FY 2002-03 to FY 2006-07.

The number of environmental samples collected increased 40.0 percent over the period shown in Table 17, growing from 1,609 in FY 2002-03 to 2,253 in FY 2006-07. In contrast, the number of other samples collected has fallen, reflecting DATCP’s increased reliance on environmental testing.

Table 17
Samples Collected

Category	FY 2002-03	FY 2003-04	FY 2004-05	FY 2005-06	FY 2006-07	Total
Environmental Samples	1,609	1,446	1,775	1,690	2,253	8,773
Cheeses	320	272	152	152	37	933
Milk	10	8	21	9	0	48
Other Dairy	61	169	51	43	59	383
Meats	94	175	80	36	40	425
Fish	58	54	49	46	29	236
Fruits, including Melon Salads	66	113	2	6	0	187
Vegetables	25	8	6	6	7	52
Deli Items, including Sandwiches and Salads	163	185	69	17	35	469
Acidified Foods	28	20	20	14	13	95
Beverages, including Juices and Bottled Water	36	31	14	22	31	134
Sushi	9	28	29	8	6	80
Containers and Plastics	0	9	0	2	0	11
City or Well Water	37	26	3	3	11	80
Other ¹	178	96	74	82	123	553
Total	2,694	2,640	2,345	2,136	2,644	12,459

¹ Most samples in this category are tested for temperature control.

Most food and environmental tests performed by DATCP were for listeria.

DATCP performs more than 56 types of tests on food samples. The ten food and environmental tests most commonly performed are shown in Table 18. Testing for listeria represented 63.0 percent of the 16,109 tests performed. Coliform, e. coli, and staph aureus are also bacteria that can cause foodborne illness. Bacterial count tests were most often performed on soft-serve ice cream.

Table 18

**Tests Performed on Food and Environmental Samples
FY 2002-03 through FY 2006-07**

Test	Number	Percentage
Listeria	10,157	63.0%
Coliform	725	4.5
Percentage Fat	500	3.1
Salmonella	448	2.8
E. Coli	426	2.6
Species	315	2.0
Percentage Moisture	299	1.9
Bacterial Count	177	1.1
Staph Aureus	163	1.0
Acidity Level (pH)	138	0.9
Other	2,761	17.1
Total	16,109	100.0%

DATCP collected fewer environmental samples in each of the past five fiscal years than it planned to collect.

As shown in Table 19, DATCP collected fewer environmental samples in each of the past five fiscal years than were anticipated in its annual plans. This was due, in part, to the higher priority given to mandated testing activities at dairy plants. The number of environmental samples collected was 91.3 percent of the number planned in FY 2004-05, but declined in each of the following two fiscal years to a low of 78.2 percent in FY 2006-07. This trend is concerning because DATCP is increasing its reliance on environmental sampling to monitor food safety but is increasingly unable to meet its testing goals.

Six of the 17 establishments that were found to have listeria in their environments were not re-sampled in a timely manner.

We found that 8,249 of the 8,773 environmental samples collected, or 94.0 percent, were tested for listeria. A pathogenic strain of listeria was identified in 34 samples from 17 establishments. According to DATCP's policies, establishments testing positive for the pathogenic strain of listeria should be visited by an inspector within one week to discuss the problem, possible sources of contamination, and strategies to address the problem. In addition, DATCP policies indicate that the establishment should be re-sampled within 28 days.

Table 19

Environmental Samples

Fiscal Year	Number Planned	Number Collected	Percentage Collected
2002-03	1,970	1,609	81.7%
2003-04	1,800	1,446	80.3
2004-05	1,944	1,775	91.3
2005-06	1,944	1,690	86.9
2006-07	2,880	2,253	78.2
Total	10,538	8,773	83.3

Although it cannot be determined from the sampling data whether the inspectors returned to the establishments to discuss proper cleaning and food handling procedures, 11 establishments were re-sampled within 28 days. However, we found that six were not re-sampled in a timely manner. Instead:

- five establishments were re-sampled an average of 70 days from the date of the initial tests showing contamination, including two that continued to show listeria in the environment at the time of the follow-up sampling; and
- one establishment was never re-sampled.

Recommendation

We recommend the Department of Agriculture, Trade and Consumer Protection report to the Joint Legislative Audit Committee by January 5, 2009, on the procedures it has implemented to:

- *increase the annual percentage of planned environmental samples that are actually collected and tested for pathogens; and*
- *improve its timeliness in following up on cases in which pathogens are identified through sampling.*

■ ■ ■ ■

Enforcing Food and Dairy Safety Requirements ■

DATCP seeks voluntary compliance with food and dairy safety regulations and addresses instances of noncompliance through a process of progressive enforcement that may include more frequent inspections and penalties for habitual violators. We reviewed DATCP's regulatory process, evaluated the effectiveness of its compliance and enforcement efforts, and compared its current efforts to the findings in our previous evaluations.

Regulatory Overview

Although the specific type and nature of regulatory functions vary across state agencies, there are standard principles common to all regulatory practices. When applied to DATCP's food and dairy safety program, they include:

- establishing a regulatory framework that strives to prevent foodborne illnesses by achieving sustained compliance with licensure and other program requirements;
- responding in a timely manner to human health risks when they are identified;
- initiating enforcement actions that are remedial, reasonable, and directly related to the actual or potential risk to human health posed by the compliance concerns identified;

- establishing enforcement procedures that are designed to prevent future noncompliance and are tailored to address the specific compliance issues identified, including placing more stringent penalties on those demonstrating repeated noncompliance; and
- ensuring that similar regulatory issues are dealt with consistently across all types of regulated entities, regardless of their location.

DATCP's regulatory philosophy emphasizes both voluntary compliance and progressive enforcement.

DATCP attempts to address these principles as part of its formal written policy document, Regulatory Philosophy, which emphasizes both voluntary compliance and progressive enforcement. In an effort to obtain voluntary compliance, DATCP first educates individuals operating food and dairy establishments about food and dairy safety regulations. In instances of noncompliance, it has a policy of using progressively more stringent enforcement actions in an effort to gain “permanent and continuous” compliance with food and dairy regulations.

Most violations of food and dairy safety regulations are identified during routine inspections.

Although violations of food and dairy safety regulations can be identified through product sampling and testing, consumer complaints, foodborne illness outbreaks, and other means, most are identified during routine inspections. If an inspector determines that an establishment is in substantial compliance with regulations, follow-up action is not needed. However, if an inspector identifies a situation that requires prompt corrective action—including a serious violation such as a broken refrigeration unit, a significant number of violations, or violations that were noted in prior inspections—the inspector may schedule a re-inspection of the establishment to ensure that adequate corrective action is taken.

DATCP has multiple enforcement tools to achieve compliance with food and dairy safety regulations, such as:

- preparing a criminal complaint for presentation to the District Attorney in the county where the establishment is located, which may result in fines of up to \$1,000 for each violation;
- issuing holding orders, which prohibit the sale or movement of food that is considered unsafe because it may be adulterated or misbranded;
- issuing a conditional license, which allows a regulated person or establishment to operate under specified terms or conditions or requires the completion of certain actions within a specified time frame;

- suspending a license or Grade A dairy farm permit; and
- revoking a license.

The primary compliance and enforcement actions used by DATCP are shown in Table 20. If an inspector determines that a re-inspection is needed, the inspector’s supervisor issues a warning letter to the establishment that states the reason for the re-inspection and whether a re-inspection fee will be charged. If the establishment has a history of noncompliance, the inspector’s supervisor may schedule an administrative conference with the establishment owner, the inspector, and other interested parties such as attorneys representing the licensed establishment. The conference’s purpose is to review the establishment’s inspection history and identify how the establishment will effectively and permanently correct violations. Although DATCP may also prepare a formal complaint that typically seeks license revocation, DATCP and the establishment’s owner typically agree to a conditional or suspended license.

Table 20

Primary Compliance and Enforcement Actions

Action	Purpose
Routine Inspection	Identifies compliance or noncompliance with food and dairy safety regulations.
Warning Letter	Sent by an inspector’s supervisor to the establishment, identifying violations of food and dairy safety regulations and specifying DATCP’s follow-up actions, such as a re-inspection or an administrative conference.
Re-Inspection	Determines if previously identified violations have been corrected. DATCP may charge a fee for re-inspections.
Administrative Conference	Includes the establishment owner, the inspector, the inspector’s supervisor, and other interested parties for the purpose of reviewing the establishment’s violation history and identifying corrective actions to be taken by the establishment.
Formal Administrative Action	Usually involves a complaint prepared by DATCP requesting that DATCP’s Secretary revoke the establishment’s license. Often DATCP and the establishment owners agree to a conditional license instead of revocation. This agreement requires the Secretary’s approval.

From FY 2002-03 through FY 2006-07, DATCP reported issuing an estimated 1,130 warning letters, holding an estimated 95 administrative conferences, placing conditions on approximately 175 licenses, and suspending approximately 165 licenses and 2,765 Grade A dairy farm permits. It did not issue any injunctions or subpoenas. From calendar year 2003 through calendar year 2007, 20 food and dairy cases resulted in a civil forfeiture and 1 licensed establishment was charged with a criminal misdemeanor for the sale of adulterated and misbranded food and for manufacturing food in an unclean environment. DATCP does not track the number of holding orders that it issues or the total number of revoked licenses.

Review of Compliance and Enforcement Cases

DATCP's regulatory approach appears effective for the vast majority of regulated establishments.

Seeking voluntary compliance from all regulated entities encourages a cooperative working relationship between DATCP and regulated establishments, and it may also limit the number of inspectors needed to ensure continued compliance with food and dairy regulations. Because 94.4 percent of routine inspections from FY 2004-05 through FY 2006-07 identified no need for follow-up action, DATCP's approach appears effective for the vast majority of regulated establishments.

In 13 of the 50 cases that we reviewed, we believe DATCP did not take timely and sufficient enforcement action.

To evaluate the effectiveness of DATCP's compliance and enforcement efforts in instances in which follow-up action was needed, we reviewed 50 cases from among those that suggested significant noncompliance with food and dairy safety regulations. These cases included 25 dairy cases—17 dairy farms and 8 dairy plants—and 25 food cases—18 retail food establishments, 6 food processors, and 1 food warehouse. We found that in 13 cases, or approximately one-fourth of those we reviewed, DATCP did not take timely and sufficient enforcement action to ensure “permanent and continuous” compliance with food and dairy safety regulations, as shown in the following five examples. While not all of these cases involved a direct threat to human health, they all represent instances in which DATCP's enforcement actions were insufficient. Appendix 1 summarizes all 13 cases.

Case 1: In September 2004, DATCP placed a Grade A dairy farm in Chippewa County under a 24-month conditional license, after 89 months of inconsistent compliance with dairy farm standards. During this 89-month period:

- DATCP conducted 29 inspections and identified 130 violations, 40 of which occurred during multiple inspections;

- issued 12 notices of intent to suspend the farm's Grade A permit; and
- twice suspended the farm's Grade A permit.

DATCP issued one farm a non-conditional license even though not all of the compliance problems had been addressed.

DATCP staff indicated the farm made corrections in order to comply with Grade A dairy farm standards when it was on the verge of losing its Grade A permit, but it "does not appear motivated to keep the standards up between inspections." Moreover, four months after temporarily suspending the farm's conditional license for four days in May 2006, DATCP issued the farm a non-conditional, or regular license, even though continuous compliance with dairy regulations had not been achieved.

At one retail food establishment, DATCP identified 111 violations over a 65-month period, including at least 42 violations that were noted during multiple inspections.

Case 2: It was not until June 2007 that DATCP held an administrative conference with the owner of a Milwaukee County retail food establishment to discuss the establishment's history of noncompliance. During 11 inspections over a 65-month period that began in February 2002, DATCP identified at least 111 violations. At least 42 violations were noted during multiple inspections. Identified violations included insufficient protection of food from contamination, the presence of insects or rodents, improper chemical storage, and inadequate hand-washing facilities.

Despite the establishment's long history of noncompliance, DATCP conducted one inspection six months after it had been scheduled. During that February 2006 inspection, DATCP identified 12 violations. At an October 2006 inspection, it identified 19 violations, including 9 that had also been found in February. However, DATCP did not conduct a re-inspection until after an inspection in April 2007 that identified 23 violations, including 14 that had also been found during the previous inspection.

Case 3: DATCP failed to follow through with enforcement action at a Grade B dairy plant in Grant County that held a license to produce dairy products for human consumption, even though it only processed animal feed. In June, August, and November 2004, DATCP held administrative conferences with the plant's owner to address concerns that the dairy plant did not meet the requirements for licensure as a dairy plant, as described in ch. ATCP 80, Wis. Adm. Code. In a letter sent to the plant after the November 2004 administrative conference, DATCP indicated that all licensing requirements were to be met by March 2005 or the dairy plant's license would not be renewed. However, even though a February 2005 inspection found that the establishment failed to meet dairy plant licensing requirements, the license was renewed in May 2005.

DATCP conducted eight re-inspections at one establishment between June 2005 and May 2007 and found the same 13 violations during each.

The violations persisted. DATCP conducted eight re-inspections between June 2005 and May 2007, for which it assessed \$2,040 in re-inspection fees, and found the same 13 violations during each, including the absence of an appropriate pasteurizer, storing whey at unsafe temperatures, and inappropriately storing fly bait near processing equipment. DATCP did not take additional enforcement action.

Case 4: It was not until June 2005 that DATCP held an administrative conference with the owners of a retail food establishment in Jefferson County to discuss its history of noncompliance. During four inspections and seven re-inspections from May 2003 through June 2005, DATCP identified a total of 95 violations, including 13 that were noted during multiple inspections. These inspections identified concerns such as improperly storing food products and insufficiently training employees in safe food handling procedures.

After numerous violations following a June 2005 administrative conference, DATCP did not take the enforcement action it said it would take.

In a June 2005 letter summarizing the administrative conference for the owners, DATCP indicated that it would conduct two re-inspections and that “failure to make positive and permanent changes will result in a complaint to be filed” against the establishment. Two re-inspections in September 2005 found numerous similar violations, including improper food temperature control, inadequate hand-washing facilities, and general sanitation and repair concerns, but DATCP did not take additional enforcement action.

One dairy farm had eight violations of its conditional license agreement.

Case 5: In August 2000, DATCP placed a Grade B dairy farm in Monroe County under a 24-month conditional license after identifying 23 milk-quality violations over a 42-month period. The farm violated the terms of its conditional license agreement eight times because of high bacteria levels, and the conditional license required a civil forfeiture or temporary license suspension when it was violated. However, the dairy farm was not penalized for one violation and there was an average lag of six months between the other seven violations and the imposition of a penalty. The final violation of the agreement occurred in July 2002, which was one month before the expiration of the conditional license.

We note that while DATCP does not always take timely or sufficient enforcement action to correct serious, habitual license violations during routine food and dairy inspections, it promptly issued warning letters in September 2004 and April 2005 to two restaurants for serving margarine instead of butter. We also recognize the need for DATCP to be judicious in the use of enforcement actions that may affect the economic viability of regulated establishments and have potential ramifications for both owners and employees. However, DATCP should be expected to use its enforcement powers to protect consumers, and apply them fairly. To ensure the safety

and quality of the human food supply they are intended to protect, the rules and regulations DATCP enforces should be applied consistently and in a manner that brings regulated entities into compliance within days or weeks, rather than years. In addition, it could be argued that a regulatory system that allows some establishments to consistently not meet the standards it was designed to enforce is unfair to the majority of establishments that comply with them and likely incur additional costs to do so.

DATCP's difficulty in effectively gaining compliance with establishments that do not willingly cooperate with its efforts is longstanding.

DATCP's difficulty in effectively gaining compliance with establishments that do not willingly cooperate with its efforts is longstanding. We noted similar concerns in our December 1983 and November 1985 audits, in which we concluded that:

- voluntary compliance was an inadequate enforcement approach for dealing with establishments that chronically violate food and dairy safety regulations;
- DATCP tolerates long periods of noncompliance by some establishments; and
- DATCP does not use all of the enforcement options available to it.

DATCP does not routinely use its statutory authority to ensure full compliance with food and dairy safety regulations.

One of the reasons DATCP's food and dairy enforcement efforts are not always effective or timely may be because inspectors do not routinely review an establishment's compliance history beyond the most recent inspection report. Doing so could help DATCP identify patterns of noncompliance and develop strategies to better address these issues in a timely manner. Moreover, although DATCP placed conditions on approximately 175 licenses from FY 2002-03 through FY 2006-07, it has not used its statutory authority to develop more effective conditional license requirements. For example, in the cases we reviewed, DATCP re-issued regular licenses to establishments that met the terms specified in their conditional licenses even if significant violations were found during the last months of the conditional license period. However, nothing in state or federal law prevents DATCP from establishing full compliance over a specified number of months as a condition of a conditional license. In fact, s. 93.06(8), Wis. Stats., appears to anticipate that such conditions will be imposed and notes that a license shall be void if compliance with food and dairy safety regulations is not achieved within a time period specified by DATCP. We question why DATCP does not routinely use this authority to ensure full compliance before re-issuing regular licenses and does not suspend licenses for progressively longer time periods after each successive violation.

We recommended in 1985 that DATCP develop monitoring procedures to ensure that clear statements of intention are communicated to the establishments and that DATCP take effective enforcement action when compliance is not achieved by the specified date. While it now appears to be providing statements of its intentions by routinely issuing warning letters and administrative conference summaries, DATCP still does not consistently provide deadlines for corrective action or take effective enforcement actions when compliance is not achieved.

In general, most of the concerns we identified in prior reports persist and continue to limit the effectiveness of DATCP's food and dairy compliance efforts because its enforcement actions are not always timely or sufficient to gain full compliance with program regulations.

Recommendation

We recommend the Department of Agriculture, Trade and Consumer Protection enhance its food and dairy enforcement activities by:

- *tracking enforcement action to ensure it is timely, progressive, and can be easily reviewed by program managers for consistency and effectiveness;*
- *requiring all inspectors to include as part of every inspection they conduct a review of an establishment's inspection history;*
- *communicating to establishments clear statements of what DATCP expects to be corrected by specified dates and its intentions if corrective action is not taken within the time period specified;*
- *following through with specified enforcement action when an establishment fails to institute corrective action within the time period specified, unless special circumstances preclude such action;*
- *including in all conditional license agreements provisions that require the establishment to achieve full compliance with regulatory requirements for a specified period of time before being eligible for a regular license; and*
- *reporting to the Joint Legislative Audit Committee by January 5, 2009, on how it has implemented these recommendations.*

Oversight of Local Retail Food Safety Regulation ■

DATCP is statutorily permitted to enter into agreements that allow certain local health departments to license and inspect retail food establishments within their jurisdictions. DATCP provides regular training and support for these local efforts. We reviewed DATCP's agreements with local health departments and examined its oversight of the local efforts.

Participation by Local Health Departments

***As of June 2007,
34 local health
departments were
regulating local retail
food establishments
under contract
with DATCP.***

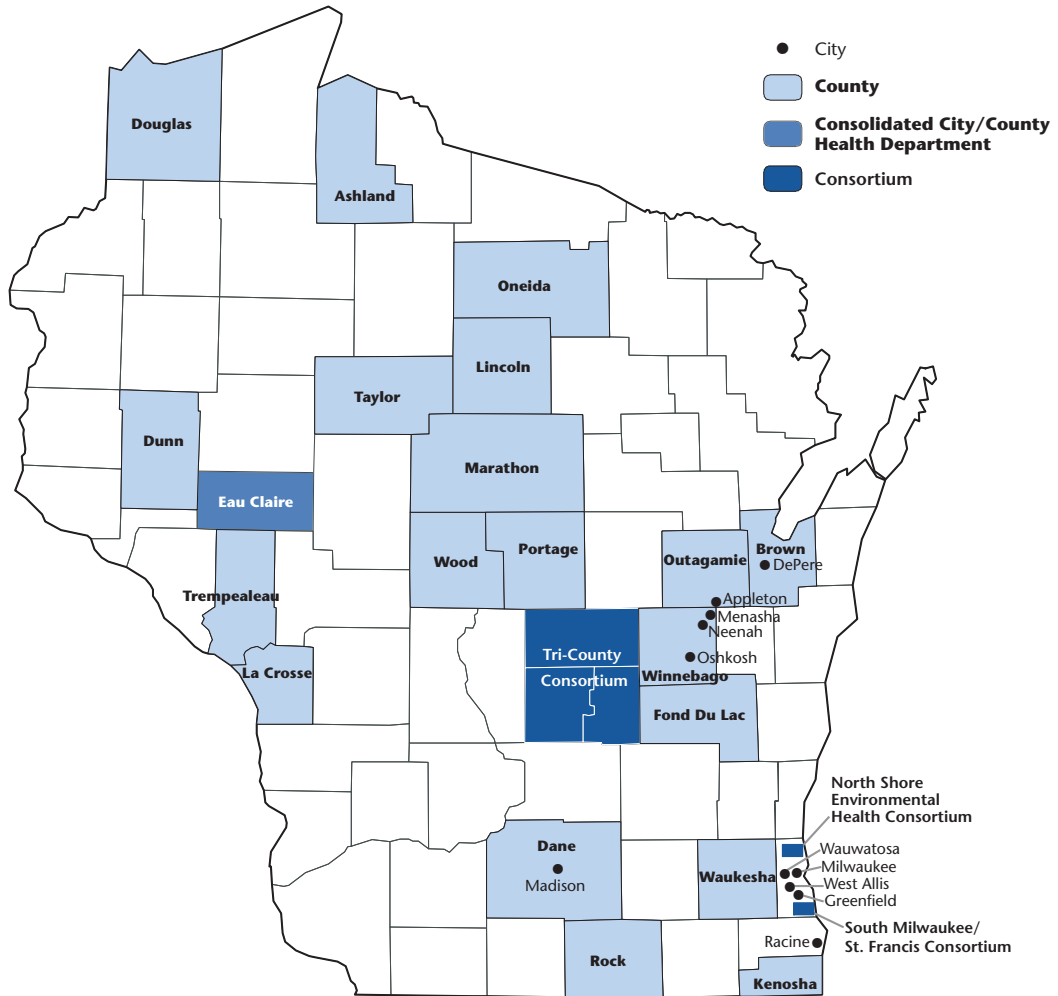
As of June 30, 2007, 34 local health departments regulated retail food establishments, as shown in Figure 1. DATCP has developed a standard agreement with these local health departments that indicates it will coordinate with DHFS to provide education and training to local staff, develop standards and approve forms used by local staff, and annually evaluate local health department performance. The agreement requires local health departments to:

- license and inspect all retail food establishments within their jurisdictions;
- investigate consumer complaints;
- collect food samples, as requested by DATCP;
- establish and collect fees;

- annually pay DATCP 10.0 percent of the license fee revenue DATCP would otherwise have received for licensing the retail food establishments;
- report to DATCP monthly on all newly licensed establishments and changes in license status; and
- maintain all licensing, investigation, inspection, and enforcement records for three years.

Figure 1

Local Health Departments Participating in the Retail Food Safety Program
June 30, 2007



To compare local safety programs with DATCP's, we interviewed officials from eight of the health departments that regulate retail food establishments, and we reviewed the agreements of all 34 local health departments that regulated retail food establishments as of June 30, 2007.

We interviewed local health department officials in Brown County, the City of De Pere, Douglas County, La Crosse County, the City of Madison, Marathon County, the City of Milwaukee, and the South Milwaukee/St. Francis Consortium. Many of those interviewed indicated their departments chose to regulate retail food establishments in order to be able to respond quickly to local food-related concerns. All of the participating local health departments also contract with DHFS to license and inspect restaurants and to conduct other environmental health regulatory activities within their jurisdictions.

In June 2007, local health departments regulated 51.7 percent of licensed retail food establishments.

As of June 30, 2007, the 34 local health departments licensed and inspected 51.7 percent of licensed retail food establishments in Wisconsin. As shown in Table 21, the City of Milwaukee was responsible for 976 of the 4,951 retail food establishments regulated by local governments, or 19.7 percent of the total.

Table 21

Retail Food Establishments Regulated by Local Health Departments
As of June 30, 2007

Local Health Department	Establishments	Percentage
City of Milwaukee	976	19.7%
Waukesha County	374	7.6
City of Madison	359	7.3
Dane County	290	5.9
Brown County	287	5.8
Rock County	271	5.5
Kenosha County	218	4.4
Marathon County	194	3.9
Outagamie County	156	3.1
Eau Claire County	136	2.7
All Other Local Health Departments	1,690	34.1
Total	4,951	100.0%

Information on the 34 local health departments' budgets and expenditures was not readily available, but detailed information on staffing and fees charged by local health departments is included in our letter report issued in January 2008. In that report, we compared DATCP's retail food licensing fees with fees charged by 26 of the 34 local health departments and found that local fees were frequently higher than those charged by DATCP. This is due, in part, to an administrative rule requirement that local health departments pay DATCP 10.0 percent of the annual license fee revenue it otherwise would have received for licensing the retail establishments.

DATCP trains local health department staff in order to ensure inspection consistency.

To help ensure consistency in conducting inspections, DATCP:

- trains local health department staff when they first begin regulating retail food establishments;
- conducts five training sessions throughout Wisconsin each year;
- holds an annual meeting to provide regulatory updates and training sessions on specific topics, such as identifying potential food safety hazards; and
- provides field training to some local inspectors.

Field training is accomplished by having at least one inspector from each local health department complete a series of three inspections with DATCP or DHFS staff during a one-year period, as well as one inspection annually for the next three years. As of June 30, 2007:

- at least one inspector in 26 of the 34 local health departments had completed the initial series of three inspections;
- 5 of the 8 health departments that did not have an inspector trained by DHFS or DATCP staff were in the first years of their contracts with DATCP; and
- 13 local health departments had completed the initial series of inspections at least three years ago, and three had at least one inspector complete a joint inspection annually for three years.

To disseminate knowledge gained from DATCP and DHFS staff, local staff who have worked with state staff complete joint

inspections with other local regulatory staff. Information was not readily available on the number who completed such joint inspections with other local staff.

Some local health departments would like more written guidance from DATCP.

DATCP appears to provide sufficient and relevant training to local health departments. Several health departments noted that joint training sessions provided by DATCP and the FDA were helpful. Most local health departments indicated that DATCP was generally responsive to their questions, but some indicated that because of DATCP's limited resources they will contact other experienced local health departments for technical assistance and that they would like more written, rather than verbal, guidance from DATCP.

Evaluating Local Health Department Performance

DATCP is required to annually review and evaluate the retail food safety efforts of each participating local health department.

DATCP is required under s. ATCP 74.09, Wis. Adm. Code, to at least annually review and evaluate the retail food safety efforts of each participating local health department. This annual review may address compliance with the terms of the agreement, including budget, staffing, training, record-keeping requirements, and a review of investigations conducted in response to consumer complaints. Once every three years, DATCP is required to inspect a representative sample of retail food establishments licensed by each local health department in order to evaluate compliance with ch. 97, Wis. Stats.

DATCP has not conducted any of the required reviews of local health departments since 2004.

We found that DATCP has not conducted any of the required reviews since 2004. Between August 2002 and June 2004, DATCP reviewed only 34.8 percent of participating programs. DATCP officials indicated they are not able to meet the requirement of annually reviewing and evaluating local programs because of staffing constraints. DATCP's efforts have been focused on working with DHFS to develop a self-reporting tool local health departments can use to report how they comply with contract requirements.

In 2006, self-reports were first mailed to local health departments. Departments are asked to report on activities in the previous fiscal year and return the forms to DHFS by September of each year. Only 14 of the 34 local health departments under contract with DATCP responded for FY 2005-06. As of January 2008, 21 of the 34 local health departments had responded for FY 2006-07. Although DATCP has the authority to conduct an investigation to verify the information submitted, it has not conducted any investigations to date.

We reviewed the reports submitted by the 21 local health departments that responded for FY 2006-07. While 11 health departments reported inspecting every retail food establishment at least once during FY 2006-07, as required, 7 reported conducting fewer inspections than the number of licensed establishments, suggesting they likely did not inspect each licensed establishment at least once during the year, and 3 did not provide information on the number of inspections they conducted.

DATCP's use of self-reporting by local health departments has not led to effective oversight.

The self-reports can aid DATCP in evaluating how local health departments implement program requirements, but they do not fulfill the administrative rule requirement that DATCP inspect a representative sample of food establishments licensed by local health departments once every three years. Further, not all local health departments have submitted the reports, and those submitted contained incomplete information. DATCP could improve its review of local efforts by ensuring local health departments report by the end of each fiscal year, and by periodically verifying that the information provided is correct. In addition, conducting the inspections of retail food establishments licensed by local health departments, as required, would allow DATCP to better assess inspection consistency.

Recommendation

We recommend the Department of Agriculture, Trade and Consumer Protection report to the Joint Legislative Audit Committee by January 5, 2009, on its plans for improving its review of local retail food safety efforts, including its plans to begin conducting inspections of a representative sample of retail food establishments licensed by local health departments, as required by administrative rule.

■ ■ ■ ■

Responding to Food Emergencies ■

DATCP is the lead state agency responsible for responding to food emergencies.

A food emergency is an incident in which the food supply is contaminated, whether accidentally or intentionally, leading to potential or actual food-related human health problems. DATCP is the lead state agency responsible for responding to foodborne illnesses, disease outbreaks, and other emergencies in which the food supply is threatened. DATCP's response to food emergencies varies based on the size, scope, and nature of the emergencies. We reviewed DATCP's response plans and examined its response to the 41 food emergencies it identified over a five-year period.

Identifying a Food Emergency

DATCP has developed response plans based on the type and scale of a food emergency.

DATCP has developed response plans based on the specific type and scale of a food emergency. Its Food Security Response Plan applies to large-scale food emergencies that originate in Wisconsin and require responses from several agencies, such as DHFS and local health departments that identify outbreaks of foodborne illness and conduct disease investigations. This plan defines the roles and responsibilities of DATCP and other responding agencies, as well as how the agencies will work together.

According to the plan, DATCP is the primary agency responsible for identifying and controlling foodborne illness or disease outbreaks. Its responsibilities include inspecting suspected food and dairy establishments; assisting with recalls of food and dairy products; tracking food and dairy products from manufacturing to distribution; taking appropriate regulatory action, such as holding, condemning, or quarantining suspected products; collecting

samples of food and dairy products suspected to be contaminated; and coordinating with other agencies and groups.

Other agencies that can become involved in a large food emergency response are:

- local and state law enforcement agencies;
- the Federal Bureau of Investigation, which would become the lead agency for any criminal investigation if it is determined that the food supply was deliberately contaminated;
- Wisconsin Emergency Management, a division of the Wisconsin Department of Military Affairs that may become involved by activating the State Emergency Operations Center, initiating and maintaining contact with affected jurisdictions, preparing reports for the Governor, receiving and acting on requests for assistance from county emergency managers, coordinating the State's response with local and national agencies, and helping to dispose of contaminated products and to transport suspected contaminated samples to laboratories;
- the FDA, which may offer assistance or take a lead role in investigating suspected food products, assist with recalls, and issue information for the media and consumers and is likely to become involved in food emergencies linked with products that have crossed state borders, or cases involving botulism;
- the federal Centers for Disease Control and Prevention, which may provide expertise in the spread of infectious disease in large populations and other public health issues, conduct laboratory testing, and issue health alerts to state health departments and healthcare providers to help identify clusters of illnesses; and
- the United States Department of Agriculture, which is responsible for regulating meat and poultry products sold across state lines and may assist states with investigations, detain suspected products, and request voluntary recalls in food emergencies involving meat or poultry from a federally inspected plant.

DATCP's Food Security Response Plan indicates that during large-scale food emergencies, a joint information center staffed by representatives of all responding agencies will be established to

provide public information and conduct media briefings. In food emergencies that cross state borders and involve the federal government, DATCP is to identify a liaison with other states and the federal government.

DATCP has also established procedures for more routine, small-scale food safety investigations. Its Food Safety Emergency Response Team Procedures Manual indicates that:

- a response will depend on the size and severity of the problem and will involve determining the type of investigation needed, gathering samples of food products, assessing the level of resources needed to respond appropriately, and determining if and when other agencies and the media need to be informed; and
- follow-up to an investigation can include issuing product hold or disposal orders, encouraging voluntary recalls, or pursuing compliance action.

With the exception of infant formula, DATCP does not have the authority to issue a recall for a contaminated food product; recalls must be issued voluntarily by the manufacturer. DATCP's procedures require a log of events and contacts to be maintained and updated throughout the food emergency, and a final written report to be submitted by all involved DATCP personnel at its conclusion. The emergency response team is also required to critique the response process.

DATCP identified 41 food emergencies from FY 2002-03 through FY 2006-07.

As shown in Table 22, DATCP identified 41 food emergencies from FY 2002-03 through FY 2006-07. As shown in Table 23, foodborne pathogens accounted for 23 of the 41 food emergencies. The most

Table 22

Food Emergencies Identified by DATCP

Fiscal Year	Food Emergencies
2002-03	14
2003-04	14
2004-05	5
2005-06	5
2006-07	3
Total	41

common type of foodborne pathogen has been listeria, which is usually discovered either through routine sample testing by DATCP or through sample testing by the manufacturer or dairy plant that is reported to DATCP. Six of the 41 food emergency cases involved human illnesses, and each affected between 1 and 61 people.

Table 23

Food Emergency Type
FY 2002-03 through FY 2006-07

	Number of Incidents
Foodborne Pathogens ¹	23
Dead or Sick Dairy Cows or Contaminated Feed	6
Storm or Fire Damage	3
Misbranding or Potential Allergen	2
Improper Pasteurization	1
Ammonia Leak	1
Other	5
Total	41

¹ Includes listeria, e. coli, brucellosis, salmonella, and campylobacter, which are all bacteria.

DATCP’s Response to Food Emergencies

We reviewed DATCP’s response to the 41 food emergencies it identified.

We reviewed DATCP’s files in order to evaluate its response to the 41 food emergencies. Although several involved extensive cooperation with other agencies, none met the criteria to be considered a large-scale food emergency as described in DATCP’s Food Security Response Plan.

In 11 of the 41 incidents, DATCP took some action to investigate, but a food safety issue was not found. For example, if the first round of testing food samples indicates the presence of a pathogen, further testing is needed for confirmation and a food emergency file is created in anticipation of a possible food emergency. This occurred in 2 of the 11 incidents. In other incidents, dairy cows had consumed contaminated feed but testing revealed their milk was unaffected, and storms had caused widespread power outages or flooding but inspectors found no damage to food or structures storing food in the affected areas.

Four of the 41 incidents were handled entirely by other agencies. For example, in 2002 a manufacturer in Minnesota issued a recall of ice cream that included an allergen that was not identified on the product's label. Although none of the affected ice cream was shipped to Wisconsin, DATCP alerted its staff.

Contaminated spinach sickened 50 Wisconsin residents and caused 1 death in 2006.

In 13 of the 41 incidents DATCP initially identified and referred a possible concern to the appropriate response agency, or DATCP played a supporting role while another agency had primary responsibility. For example, spinach contaminated with e. coli sickened 50 Wisconsin residents and caused 1 death in fall 2006. Because the spinach was produced in California, the FDA was the primary investigator, but DATCP inspectors were instructed to place a hold on any spinach they observed being sold while regularly inspecting retail establishments.

The remaining 13 incidents were primarily handled by DATCP, although several involved other agencies. Eight involved foodborne pathogens, although no associated illnesses were reported. Two involved human illnesses from foodborne pathogens: a child sickened from milk from an unidentified source, and 61 people sickened by cheese curds made from unpasteurized milk by an unlicensed producer, which was the largest number of reported illnesses that occurred in Wisconsin as a result of a food emergency during our review period. The remaining three incidents involved an ammonia leak at a freezer warehouse, fire damage to another freezer warehouse, and improper pasteurization of cheese and malfunctioning equipment at a dairy plant. Appendix 2 describes these 13 cases in more detail.

Based on our file review, DATCP appears to have taken appropriate action in responding to food emergency cases.

Based on our file review, DATCP appears to have taken prompt, appropriate action in responding to 40 of the 41 incidents, including issuing holds, disposing of contaminated products, conducting re-inspections, collecting and analyzing samples, and pursuing formal legal or compliance action when necessary. We could not determine whether appropriate action was taken in only one incident. In October 2002, a sandwich that was sampled as part of DATCP's routine testing efforts tested positive for listeria. DATCP's sampling database indicates that resampling occurred eight days later, and those samples showed no presence of listeria. However, from the available documentation we could not determine whether appropriate action had been taken in response to the positive listeria result, such as requesting a recall, ensuring that a thorough cleaning of food contact surfaces was routinely performed, or re-inspecting the establishment. DATCP was unable to provide additional information on this incident.

Only 1 of the 41 food emergency files contained the required final written report.

In addition, we found that DATCP staff are not following all of the procedures in the Food Safety Emergency Response Team Procedures Manual, including keeping a log of events and contacts during a food emergency, critiquing the process, and preparing a written report after a case is closed. We found that only 1 of the 41 files contained a final written report, which appeared to have been written primarily by a local health department. Although the 41 files contained e-mail messages, laboratory result sheets, hand-written notes, memoranda, and other assorted documents, it was frequently difficult to determine why and when the food emergency investigation began, which other agencies were involved and the roles they played, the actions DATCP took, and how the food emergency was resolved. While DATCP staff were eventually able to provide information that was not included in the files, this information was not readily available but could be a useful management tool for DATCP if it were available in a single location.

Recommendation

We recommend the Department of Agriculture, Trade and Consumer Protection report to the Joint Legislative Audit Committee by January 5, 2009, on its efforts to ensure compliance with the Food Safety Emergency Response Team Procedures manual.

■ ■ ■ ■

Appendix 1

DATCP Compliance and Enforcement Cases

FY 2002-03 through FY 2006-07¹

Establishment Type	County	Areas of Noncompliance	Issue
Grade A Dairy Farm	Chippewa	130 violations were found during 29 inspections over an 89-month period; 40 violations were found during multiple inspections.	Lack of timely enforcement
Food Processor and Dairy Plant	Dodge	318 violations were found during 8 inspections over a 10-month period; 54 violations were found during multiple inspections.	Lack of timely enforcement
Grade B Dairy Plant	Grant	Failed to meet the requirements of its dairy plant license, and DATCP found the same 13 violations during 8 re-inspections over a 24-month period. DATCP did not issue a complaint.	Insufficient enforcement actions
Grade B Dairy Farm	Iowa	44 milk quality violations were reported over a 39-month period, and 4 violations of the conditional license were found over a 24-month period.	Insufficient enforcement action
Grade B Dairy Plant	Iowa	The plant allowed substandard milk into the food chain on 37 occasions and failed to report milk quality test results to DATCP within the required time frames on 80 occasions over a 13-month period. DATCP did not issue a complaint.	Insufficient enforcement action
Retail Food Establishment	Jefferson	95 inspection violations were found during 11 inspections over a 24-month period; 13 were found during multiple inspections. Corrections were not made after 2 subsequent re-inspections. DATCP did not issue a complaint, despite informing the establishment that it would do so.	Insufficient enforcement action

Establishment Type	County	Areas of Noncompliance	Issue
Grade B Dairy Farm	Marathon	49 inspection violations were found during 17 inspections, and 26 milk-testing violations were reported over a 50-month period.	Lack of timely enforcement
Retail Food Establishment	Marinette	At least 133 violations were found during 14 inspections over a 61-month period; at least 49 violations occurred more than once; 1 inspection occurred 3 months and another 9 months after the scheduled date, despite the long history of violations.	Lack of timely enforcement
Retail Food Establishment	Milwaukee	At least 111 violations were found during 11 inspections over a 65-month period; at least 42 violations occurred more than once.	Lack of timely enforcement
Food Processor	Milwaukee	116 violations were found during 8 inspections over a 24-month period. After an administrative conference, DATCP informed the establishment that violations on 4 consecutive inspections would result in further enforcement action. However, action was not taken until violations were noted during 6 consecutive inspections.	Insufficient enforcement action
Grade B Dairy Farm	Monroe	23 milk quality violations were reported over a 42-month period, and 8 violations of the conditional license over a 24-month period.	Insufficient enforcement action
Grade A Dairy Farm	Pierce	55 violations were found during 17 inspections, including 20 violations found at multiple inspections, and 29 milk quality violations were reported over a 42-month period.	Lack of timely enforcement
Grade B Dairy Farm	Trempealeau	93 violations were found during 12 inspections over a 97-month period, and 68 milk quality violations were reported over a 69-month period.	Lack of timely enforcement

¹ All cases had at least one compliance action between FY 2002-03 and FY 2006-07, but we included the relevant inspection and enforcement history before FY 2002-03 in our analysis.

Appendix 2

Food Emergencies Handled Primarily by DATCP

FY 2002-03 through FY 2006-07

	Description
June 2006	A campylobacter bacteria outbreak from unpasteurized cheese curds sickened 61 people in Ashland County; multiple agencies were involved in the investigation, including the Ashland County Health and Human Services Department. DATCP visited the unlicensed producer, issued a cease and desist order, visited area dairy farms to determine the source of the raw milk, ordered the farm to cease distribution of raw milk to unlicensed plants, and collected and tested samples of raw milk and cheese curds.
October 2005	An ammonia leak occurred in a freezer warehouse in Dane County. DATCP issued a holding order on several products being stored in the freezer, and all meat and poultry products were held for federal inspectors. Wrappers and cardboard were sampled; no ammonia odors were detected. Federal and DATCP inspectors moved products from one freezer to another area to see if the ammonia odor would dissipate; it did, and the federal inspectors did not identify any adverse effects on the food products. Therefore, DATCP issued a holding order release.
October 2005	A dairy plant in Dodge County was found to have problems with broken pasteurizer seals and selling cheese made from milk that had not been properly pasteurized. The producer signed a voluntary compliance agreement that required the plant to contract with an independent company to review the pasteurization system and to notify DATCP immediately whenever the system malfunctions. The affected products were recalled by the producer and destroyed.
February 2004	Listeria was found in butter collected during routine sampling at a dairy plant in Dane County. Additional samples taken in February 2004 also tested positive for listeria, and the plant issued a recall. Further samples taken six days later continued to show the presence of listeria, and an additional joint inspection with the FDA revealed ongoing sanitary problems. The dairy plant signed a special order requiring it to repair equipment, establish a sampling and testing program, and hire a food safety consultant. The dairy plant went out of business in April 2005. No associated illnesses were reported.
November 2003	A food processor in Dodge County reported to DATCP a positive test for listeria in a ready-to-eat snack cheese and then issued a voluntary recall. DATCP collected samples, but none showed signs of contamination. DATCP required the processor to suspend production for three days or until samples from two different products produced on two different days were negative for listeria, which occurred.
November 2003	Sandwiches and environmental samples from a food processor in Waukesha County tested positive for listeria. The establishment issued a voluntary recall and shut down for four days. DATCP verified disposal of the affected sandwiches and allowed the processor to reopen.
July 2003	Samples of delicatessen salads from a retail establishment in Lincoln County tested positive for listeria. Follow-up samples were collected on three more dates, and listeria and high coliform problems were found. DATCP sent a warning letter to the establishment and conducted a re-inspection, during which products were sampled and environmental samples were collected. Testing results found no further evidence of listeria. No illnesses were reported.
February 2003	Because of problems with listeria, a food processor in Dodge County agreed to a special order requiring it to notify DATCP if any pathogen was identified by a positive test. Testing revealed the presence of listeria in a cheese spread, which was reported to DATCP. The processor issued a recall. Under the terms of the special order, the processor hired an outside expert to review and improve its food safety plans. Physical changes to the establishment were reviewed and approved by DATCP.

	Description
January 2003	A fire damaged a large frozen food warehouse in La Crosse County. A DATCP inspector was on site for four days to inspect all food leaving the warehouse. All contaminated food was ordered to be destroyed.
October 2002	A sandwich sampled from a food processor in Waukesha County tested positive for listeria. According to the food emergency file, re-inspection and additional sampling were scheduled. However, the file contained no documentation on whether this occurred, and DATCP was unable to provide any additional information confirming re-inspection or additional sampling.
September 2002	Milk from a dairy farm in Rock County tested positive for toxins. A DATCP inspector visited the farm and collected additional raw milk samples, which DATCP analyzed, and toxins were again found. DATCP ordered the milk containing toxins to be dumped.
August 2002	A dairy plant in Ozaukee County reported a positive listeria test on a vat of cheese that had already been shipped out of state. DATCP issued a holding order on the cheese. A DATCP inspector visited the plant and collected additional samples. One environmental sample tested positive for listeria. The dairy plant recalled and disposed of the affected cheese.
August 2002	A child in Milwaukee County became ill from campylobacter bacteria after drinking raw milk. DATCP analyzed a sample of the milk, which tested positive for campylobacter bacteria. The woman who served the milk to the child would not disclose the milk source. The case was closed because DATCP could not trace its source.



State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary

May 21, 2008

Janice Mueller, State Auditor
Legislative Audit Bureau
22 E. Mifflin Street, Ste. 500
Madison, Wisconsin 53703

Dear Ms. Mueller:

Thank you for the opportunity to comment on the audit of Wisconsin's food and dairy safety programs administered by the Department of Agriculture, Trade and Consumer Protection (DATCP). Those of us in the business of protecting food safety often say that our nation has the safest food supply in the world, and it is true. However, new challenges arise every day. Consumers expect us to prevent food-borne illnesses – not simply respond to them. Therefore, we can never stop looking for ways to improve our food safety system. That is why this audit is important.

The Wisconsin Department of Agriculture, Trade and Consumer Protection, Division of Food Safety does not work in isolation. Food safety relies on a system that stretches between state agencies, down to local health departments, up to federal agencies, and even across oceans and national borders. Because food distribution and sale are not restricted by political or geographic boundaries, we need to have a food safety system that integrates into this national and international context.

Two questions underlie this audit: "Is DATCP's food and dairy safety program sound in its philosophy, design and performance?" and "Are there areas where the program can or should improve?"

We are pleased, but not surprised, that the answer to the first question is "yes." The report notes that DATCP seeks voluntary compliance with food and dairy safety regulations and addresses instances of noncompliance through progressive enforcement, and concludes:

DATCP's regulatory approach appears effective for the vast majority of regulated establishments.

As the report states, we licensed nearly 29,300 food and dairy entities in FY 2006-07. Less than a quarter of these were food retailers, processors and warehouses. The rest supported our dairy industry: dairy farms and dairy plants, and professionals such as cheesemakers and graders. The dairy sector is a \$20.6 billion slice of Wisconsin's economy, providing nearly five percent of our jobs. We are not only protecting public health; we are also protecting economic health. And though we believe the department's food and dairy safety programs equally benefit consumers and food and dairy industries, industry fees provide more than half of the funding for this food safety and consumer protection program.

Agriculture generates \$51.5 billion for Wisconsin

May 21, 2008

-2-

We have made changes in recent years to improve our performance and make the best use of our resources:

- We have adopted a performance-based farm inspection system for Grade A dairy farms.
- We developed an annual sampling plan to focus and support our food safety inspection system. In fact, we increased environmental sampling by 40 percent during the audit period.
- Contracting with local health departments to inspect food retailers keeps regulation close to the customer, gives our inspectors more time to focus on dairy farms and food processors in those areas, and builds a partnership that makes for more effective responses when food-borne illness outbreaks occur.

Turning to that second question – can and should we improve? – Again, the answer is “yes.” We believe the audit report offers constructive recommendations, and we will strive to implement them. Any system, no matter how sound, can and should seek opportunities to improve. Most notably, we will strive to improve the time necessary to gain compliance in our enforcement cases.

We would like to point out that not all violations are equal. The report portrays the cases cited as if they all present an equal risk to public health. Of the thirteen cases outlined in the report, eight of these cases involved issues that posed only minimal food safety risks, if any at all. Only five had potential to become food safety concerns, and none involved issues that demanded a swift response to contain an actual food safety threat. And it is important to note, the end result of all of these cases was compliance by the regulated farm or business.

We also note that when faced with circumstances that truly had the potential to adversely impact the safety of the food supply, the department did well. When discussing emergency response situations, which require immediate response to contain or mitigate an actual food safety threat, the audit notes:

DATCP appears to have taken appropriate action in responding to food emergency cases.

Though as noted in this audit, there are program improvements that should and will be made, we are proud of the professional and efficient work done by our Division of Food Safety staff in the areas of food safety and consumer protection.

Finally, we thank you for the professionalism and courtesy shown by your audit staff. We especially appreciate the extra effort your staff made to understand the nature and complexity of the food safety program. We also appreciate the fact that the auditors were willing to adjust their schedules to accommodate our workload, allowing our program staff to carry out their daily responsibilities with minimal disruption.

We believe your audit recommendations are instructive, and we will use them as we continue to improve our food safety program.

Sincerely,



Rod Nilsestuen
Secretary