

Office of the Auditor General
Performance Audit Report

Bottled Water Regulation
Michigan Department of Agriculture and Rural Development and
Department of Environmental Quality

January 2017

State of Michigan Auditor General
Doug A. Ringler, CPA, CIA

The auditor general shall conduct post audits of financial transactions and accounts of the state and of all branches, departments, offices, boards, commissions, agencies, authorities and institutions of the state established by this constitution or by law, and performance post audits thereof.

Article IV, Section 53 of the Michigan Constitution



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Report Summary

Performance Audit

Bottled Water Regulation

Michigan Department of Agriculture and Rural Development (MDARD) and Department of Environmental Quality (DEQ)

Report Number:
791-0225-16

Released:
January 2017

MDARD is responsible for registering and periodically inspecting water bottlers and water dispensing machines in Michigan. DEQ's approval of the water source is needed to produce and sell bottled water in Michigan. As of April 2016, 52 in-State bottlers, 115 out-of-State bottlers, 28 out-of-country bottlers, and 675 water dispensing machines were registered with MDARD.

Audit Objective			Conclusion
Objective #1: To assess the effectiveness of MDARD and DEQ's efforts to register and inspect water bottlers and water dispensing machines.			Moderately effective
Findings Related to This Audit Objective	Material Condition	Reportable Condition	Agency Preliminary Response
MDARD did not fully comply with its policy to conduct routine inspections of water bottlers and establishments with water dispensing machines on a timely basis. We noted 587 (22%) overdue inspections of water bottlers or establishments with dispensing machines during our audit period (Finding #1).		X	Agrees
MDARD did not actively pursue the identification and enforcement of unregistered bottled water products sold in Michigan to help ensure fee payment and compliance with regulatory requirements (Finding #2).		X	Agrees

Audit Objective		Conclusion	
Objective #2: To assess the sufficiency of MDARD and DEQ's efforts to ensure that water sold in bottles and through dispensing machines for human consumption complies with selected water quality standards established by federal law.		Sufficient, with exceptions	
Findings Related to This Audit Objective	Material Condition	Reportable Condition	Agency Preliminary Response
MDARD should implement procedures to ensure that water from dispensing machines is periodically tested for compliance with water quality standards. Otherwise, contamination issues could go undetected (<u>Finding #3</u>).		X	Agrees

A copy of the full report can be obtained by calling 517.334.8050 or by visiting our Web site at: www.audgen.michigan.gov

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January 18, 2017

Mr. Fred Walcott, Chair
Michigan Commission of Agriculture and Rural Development
and
Ms. Jamie Clover Adams, Director
Michigan Department of Agriculture and Rural Development
and
Ms. C. Heidi Grether, Director
Department of Environmental Quality
Constitution Hall
Lansing, Michigan

Dear Mr. Walcott, Ms. Clover Adams, and Ms. Grether:

I am pleased to provide this performance audit report on Bottled Water Regulation, Michigan Department of Agriculture and Rural Development and Department of Environmental Quality.

We organize our findings and observations by audit objective. Your agency provided preliminary responses to the recommendations at the end of our fieldwork. The *Michigan Compiled Laws* and administrative procedures require an audited agency to develop a plan to comply with the recommendations and submit it within 60 days of the date above to the Office of Internal Audit Services, State Budget Office. Within 30 days of receipt, the Office of Internal Audit Services is required to review the plan and either accept the plan as final or contact the agency to take additional steps to finalize the plan.

We appreciate the courtesy and cooperation extended to us during this audit.

Sincerely,

A handwritten signature in black ink that reads "Doug Ringler". The signature is written in a cursive, flowing style.

Doug Ringler
Auditor General

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AUDIT OBJECTIVES, CONCLUSIONS, FINDINGS, AND OBSERVATIONS

REGISTRATION AND INSPECTION OF WATER BOTTLERS AND WATER DISPENSING MACHINES

BACKGROUND

The Michigan Department of Agriculture and Rural Development (MDARD) is responsible for registering and periodically inspecting water bottlers and water dispensing machines to ensure that water sold in bottles or through water dispensing machines complies with State and federal regulations. To produce and sell bottled water in Michigan, an applicant must obtain Department of Environment Quality (DEQ) approval for the water source and obtain a food establishment license from MDARD.

The assurance of the safety of bottled water is a part of the overall food and dairy safety regulatory structure. Inspection work related to bottled water is mostly done as part of broader establishment visits made to ensure overall food safety at processing plants, warehouses, and retail stores. When a food establishment is licensed, it is placed on an inspection frequency based on the level of risk of the food operations in the establishment. For example, a large beverage processing plant may be high risk and inspected every 6 months, whereas a small grocery store may be low risk and inspected every 18 months. Bottled water, as a stand-alone item, would typically be considered low risk and scheduled for an 18-month inspection frequency.

MDARD collects a \$25 annual fee for each registered bottler label and each registered water dispensing machine plus a \$25 late fee for registrations renewed after April 30 of each year.

AUDIT OBJECTIVE

To assess the effectiveness* of MDARD and DEQ's efforts to register and inspect water bottlers and water dispensing machines.

CONCLUSION

Moderately effective.

FACTORS IMPACTING CONCLUSION

- Our testing of registrations for 13 bottlers and 40 dispensing machines disclosed no exceptions.
- MDARD performed 2,056 (78%) of the inspections for the population of bottlers and dispensing machines on time.
- Reportable conditions* related to improved timeliness of routine inspections and identification and enforcement of unregistered bottled water products (Findings #1 and #2).

*See glossary at end of report for definition.

FINDING #1

Timeliness of routine inspections could be improved.

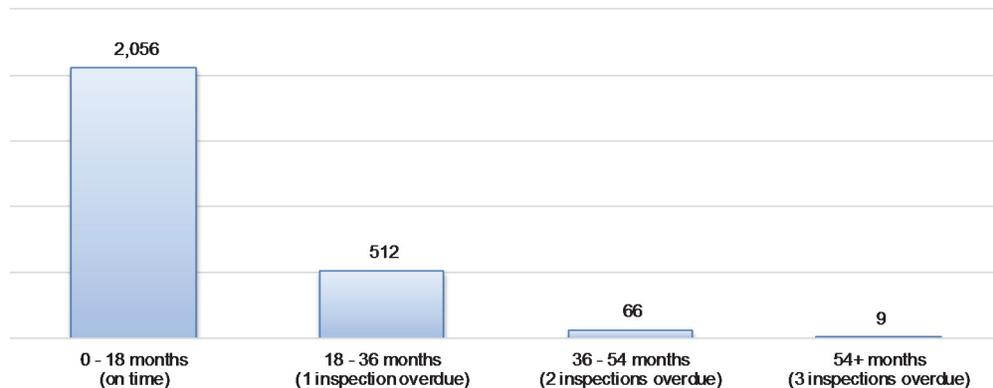
MDARD did not fully comply with its policy to conduct routine inspections of water bottlers and establishments with water dispensing machines on a timely basis.

MDARD Food and Dairy Division (FDD) policy 01.43 established a risk-based inspection schedule with a targeted routine inspection frequency of every 18 months for low-risk establishments. Inspectors who are unable to complete inspections in accordance with the inspection frequency must prioritize their work to ensure that no establishments have three or more overdue routine inspections.

MDARD did not:

- a. Always conduct timely inspections of water bottlers and establishments with water dispensing machines.

For the 2,643 inspections conducted by MDARD during our audit period, 587 (22%) were one or more routine inspections overdue. The following graph illustrates the timeliness of inspections completed during our audit period:



- b. Conduct inspections of certain establishments with water dispensing machines because they were not required to have a food establishment license.

Establishments without a food license have never been inspected nor are they scheduled for inspection.

MDARD's risk-based inspection software generates and tracks inspections only for food establishments. Therefore, dispensing machines at establishments without a food establishment license have never been inspected and are not scheduled to be inspected. We identified 18 such establishments that have not been inspected.

Establishments may be exempt from licensure if they meet specific requirements. For example, gift shops and gas stations may not be required to have a license if they sell non-potentially hazardous food that is prepackaged and incidental in amount.

RECOMMENDATION

We recommend that MDARD fully comply with its policy to conduct routine inspections of water bottlers and establishments with water dispensing machines on a timely basis.

**AGENCY
PRELIMINARY
RESPONSE**

MDARD provided us with the following response:

MDARD concurs with the finding and acknowledges the Office of the Auditor General's (OAG's) audit finding regarding past due inspections. MDARD's Food and Dairy Programs received an OAG audit in 2013 that contained recommendations to improve overall food establishment inspection frequency. Since that audit, a corrective action plan has been developed, funded, and partially implemented to increase staff and staff performance and improve technology. Completing implementation of this plan is expected to get all food establishment inspections conducted, as scheduled, by May 1, 2020.

FINDING #2

Identification and enforcement needed of unregistered bottled water products.

MDARD did not actively pursue the identification and enforcement of unregistered bottled water products sold in Michigan. As a result, MDARD did not have assurance that bottlers paid the required annual product registration fees and that their products complied with regulatory requirements.

MDARD FDD policy 01.19 requires that each unique brand of bottled water must be registered with FDD prior to the sale or offering for sale of the product. MDARD FDD policy 01.20 states that inspectors are not expected to make special trips or expend large amounts of time investigating registrations, but registrations should be checked during routine inspections.

MDARD collects a \$25 annual fee for each registered product label plus a \$25 late fee for registrations renewed after April 30 of each year. However, a fine is not assessed for failure to register.

We conducted site visits to 71 establishments with bottled water products offered for sale and identified 20 unregistered bottled water products. Increasing the time spent identifying unregistered products would help MDARD ensure that the State collects the required annual product registration fees and that bottlers comply with federal regulations. Also, to further compliance, MDARD may consider seeking legislative authority to assess and collect fines for bottlers that do not register bottled water products.

RECOMMENDATION

We recommend that MDARD actively pursue the identification and enforcement of unregistered bottled water products sold in Michigan.

AGENCY PRELIMINARY RESPONSE

MDARD provided us with the following response:

The results of this audit have led the Food and Dairy Division to believe that the current overall registration, inspection and testing program for bottled water could benefit from a program review. We believe this review will help provide a framework for a more effective and efficient system to assure the safety of bottled water and other foods and beverages that use water as a major component.

MDARD will review whether there is a public health business case by December 31, 2017 to continue to require registration of individual water labels. This review may result in policy, procedure, and law changes. Once any changes are made, the registrations will be monitored and maintained current in accordance with policy and law by December 31, 2018.

WATER QUALITY TESTING OF IN-STATE BOTTLERS AND WATER DISPENSING MACHINES

BACKGROUND

MDARD policy requires inspection of in-State water bottlers every 18 months. MDARD inspects water dispensing machines, normally found in grocery stores, at the time of the store's routine food establishment inspection every 6, 12, or 18 months in accordance with a risk-based inspection schedule.

AUDIT OBJECTIVE

To assess the sufficiency of MDARD and DEQ's efforts to ensure that water sold in bottles and through dispensing machines for human consumption complies with selected water quality standards established by federal law.

CONCLUSION

Sufficient, with exceptions.

FACTORS IMPACTING CONCLUSION

- Our testing of water sold in bottles and through water dispensing machines disclosed that the water complied with selected water quality standards established by federal law.
- Our sample of water from 50 water dispensing machines and 40 bottlers disclosed a minimal number of exceptions, including one sample that was positive for total coliforms. The rest of the samples had results below the reportable level (see Exhibit #1 for water quality testing results).
- Reportable condition related to the need to expand inspection procedures (Finding #3).

FINDING #3

Need to expand inspection procedures.

MDARD can help safeguard public health by testing water from dispensing machines.

MDARD should implement procedures to ensure that water from dispensing machines is periodically tested for compliance with water quality standards.

MDARD FDD policy 01.20 requires that all bottled water and water from dispensing machines meet federal regulations and the Michigan Safe Drinking Water Act (Public Act 399 of 1976). Water sold from dispensing machines must meet the same labeling and quality standards as bottled water.

MDARD FDD Field Guide procedure FG02.06 states that during routine evaluation of water bottling plants, inspectors must collect and submit one sample of each water product manufactured by the plant. The procedure states that water dispensing machines may also be sampled.

During a food establishment inspection, an inspector verifies a water dispensing machine's registration, reviews the maintenance and inspection log, and performs a visual inspection. However, MDARD does not collect and test water samples from the dispensing machines.

Water dispensing machines should meet the same water quality standards as bottled water. Collecting samples from water dispensing machines would allow MDARD to identify contamination issues that could have gone undetected.

We sampled water from 50 of the 616 registered dispensing machines and had DEQ run tests for water quality. Although our samples met standards required by federal regulation, MDARD should periodically test water samples to obtain further assurance that water sold from dispensing machines continues to meet water quality standards.

RECOMMENDATION

We recommend that MDARD implement procedures to ensure that water from dispensing machines is periodically tested for compliance with water quality standards.

AGENCY PRELIMINARY RESPONSE

MDARD provided us with the following response:

MDARD will review whether there is a public health business case by December 31, 2017 to require routine sampling of individual dispensing machines. Should that be determined to be a needed public health protection, MDARD will determine what types of analysis are required, the frequency of sampling, who will be required to collect samples, and how sample results will be monitored and enforced. This review may result in policy and law changes. Once any changes are made, the sampling will be conducted in accordance with policy and law by December 31, 2018.

SUPPLEMENTAL INFORMATION

BOTTLED WATER REGULATION

Michigan Department of Agriculture and Rural Development and Department of Environmental Quality

Results of Water Quality Testing

	<u>Total Coliforms/ E. Coli</u>	<u>Lead</u>	<u>Nitrate</u>	<u>Nitrite</u>
Maximum contaminant level (MCL)	E. coli positive	0.005 mg/L	10 mg/L	1 mg/L
Water Dispensing				
Machine Samples:				
1 - 9	Not detected	Not detected	Not detected	Not detected
10	Not detected	Not detected	0.5 mg/L	0.15 mg/L
11 - 13	Not detected	Not detected	Not detected	Not detected
14 - 23	Not detected	Not detected	Not detected	Not detected
24	Not detected	Not detected	0.4 mg/L	0.17 mg/L
25 - 32	Not detected	Not detected	Not detected	Not detected
33	Not detected	0.001 mg/L	Not detected	Not detected
34 - 35	Not detected	Not detected	Not detected	Not detected
36	Not detected	Not detected	1 mg/L	0.2 mg/L
37 - 45	Not detected	Not detected	Not detected	Not detected
46	Not detected	Not detected	Not detected	0.05 mg/L
47 - 50	Not detected	Not detected	Not detected	Not detected
Water Bottler Samples:				
51 - 52	Not detected	Not detected	Not detected	Not detected
53	Not detected	Not detected	0.17 mg/L	Not detected
54	Not detected	Not detected	Not detected	Not detected
55	Not detected	Not detected	0.6 mg/L	Not detected
56	Not detected	Not detected	Not detected	Not detected
57	Not detected	0.004 mg/L	< 1 mg/L	< 1 mg/L
58 - 60	Not detected	Not detected	Not detected	Not detected
61	Not detected	Not detected	1.5 mg/L	Not detected
62	Not detected	Not detected	0.5 mg/L	Not detected
63	Not detected	Not detected	0.21 mg/L	Not detected
64	Not detected	Not detected	0.21 mg/L	Not detected
65 - 69	Not detected	Not detected	Not detected	Not detected
70	Not detected	Not detected	3.6 mg/L	< 0.2 mg/L
71 - 73	Not detected	Not detected	Not detected	Not detected
74	Not detected	Not detected	0.9 mg/L	Not detected
75 - 79	Not detected	Not detected	Not detected	Not detected
80	Not detected	Not detected	0.5 mg/L	Not detected
81 - 82	Not detected	Not detected	Not detected	Not detected
83	Positive*	Not detected	Not detected	Not detected
84 - 87	Not detected	Not detected	Not detected	Not detected
88	Not detected	Not detected	1.7 mg/L	Not detected
89	Not detected	Not detected	0.8 mg/L	Not detected
90	Not detected	Not detected	0.9 mg/L	Not detected

* Sample 83 tested "Positive" for total coliforms, but E. coli was not found.

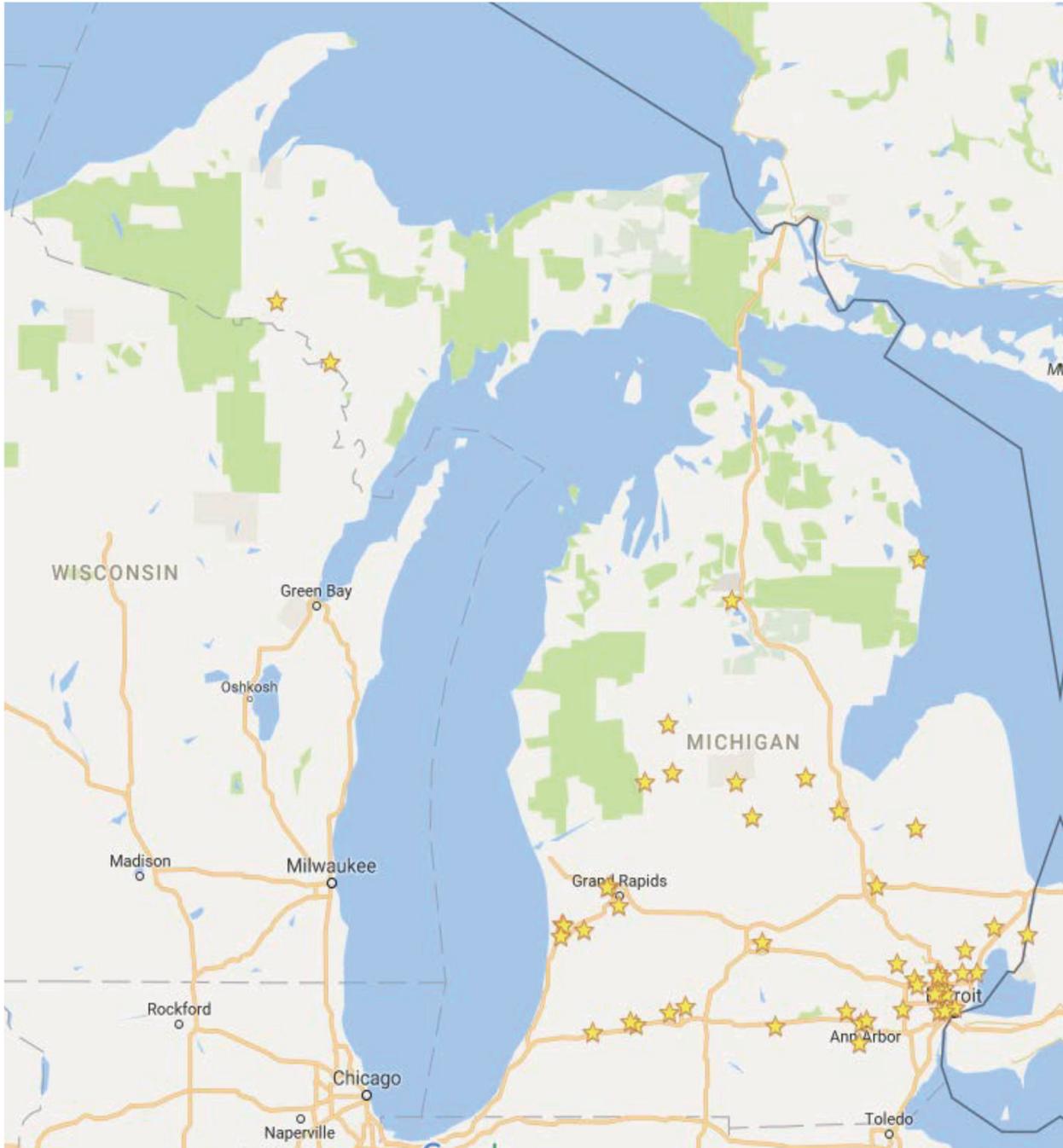
Source: The Office of the Auditor General (OAG) prepared this exhibit from water samples drawn by the OAG and tested for water quality by DEQ. Maximum contaminant levels are based on the *Code of Federal Regulations*.

	<u>Total Coliforms/ E. Coli</u>	<u>Lead</u>	<u>Nitrate</u>	<u>Nitrite</u>
Water Dispensing Machine Results:				
Between 0 and MCL	0	1	3	4
Exceeded MCL	0	0	0	0
Percent that exceeded MCL	0	0	0	0
Water Bottler Results:				
Between 0 and MCL	0	1	13	2
Exceeded MCL	0	0	0	0
Percent that exceeded MCL	0	0	0	0
Total Water Quality Results:				
Between 0 and MCL	0	2	16	6
Exceeded MCL	0	0	0	0
Percent that exceeded MCL	0	0	0	0

BOTTLED WATER REGULATION

Michigan Department of Agriculture and Rural Development and Department of Environmental Quality

Map of In-State Water Bottlers



Source: The Office of the Auditor General prepared this exhibit using data from MDARD.

AGENCY DESCRIPTION

Title 21, Parts 110, 129, and 165 of the *Code of Federal Regulations** (CFR) contain U.S. Food and Drug Administration (FDA) regulations applicable to bottled water facilities. Part 110 pertains to good practices in manufacturing, packaging, or holding human food. Part 129 pertains to the processing and bottling of drinking water. Part 165 pertains to the requirements for specific standardized beverages (such as allowable levels of contaminants and the accepted testing methodologies).

MDARD's Central Licensing Unit is responsible for the licensing of food establishments and the registration of water bottlers and water dispensing machines. Its primary objective is to ensure that all water sold in bottles or through water dispensing machines is registered with the State and that these prospective water vendors comply with federal regulations.

As part of the registration process, DEQ's Office of Drinking Water and Municipal Assistance is responsible for approving the applicant's source water. FDD is responsible for the inspections of registered water bottlers and water dispensing machines. The following table presents the number of registered bottlers and dispensing machines as of April 2016:

In-State bottlers (see map in Exhibit #2)	52
Out-of-State bottlers	115
Out-of-country bottlers	28
Water dispensing machines	675

**See glossary at end of report for definition.*

AUDIT SCOPE, METHODOLOGY, AND OTHER INFORMATION

AUDIT SCOPE

To examine the program and other records related to bottled water regulation in Michigan. We conducted this performance audit* in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

PERIOD

Our audit procedures, which included a preliminary survey, audit fieldwork, report preparation, analysis of agency responses, and quality assurance, generally covered October 1, 2013 through June 30, 2016.

METHODOLOGY

We conducted a preliminary survey of bottled water regulation to formulate a basis for defining our audit objectives and scope. During our preliminary survey, we:

- Interviewed MDARD and DEQ management and staff to obtain an understanding of bottled water regulations.
- Reviewed MDARD policies and State laws that regulate bottled water in Michigan.
- Observed an in-State water bottler inspection to gain an understanding of the inspection process.

OBJECTIVE #1

To assess the effectiveness of MDARD and DEQ's efforts to register and inspect water bottlers and water dispensing machines.

To accomplish this objective, we:

- Selected random samples of water bottlers and water dispensing machine registrations.
- Reviewed inspections of in-State water bottlers and water dispensing machines.
- Analyzed inspection data to assess the frequency of inspections of water bottlers and establishments with bottled water dispensing machines.

**See glossary at end of report for definition.*

OBJECTIVE #2

To assess the sufficiency of MDARD and DEQ's efforts to ensure that water sold in bottles and through dispensing machines for human consumption complies with selected water quality standards established by federal law.

To accomplish this objective, we:

- Selected random samples of water bottlers and water dispensing machines.
- Traveled to 71 various businesses throughout the State to purchase randomly selected samples of bottled water and water from dispensing machines.
- Collected water samples to test for water coliforms, automated partial chemistry, calcium/magnesium/sodium, and lead at a DEQ laboratory.

CONCLUSIONS

We base our conclusions on our audit efforts and any resulting material conditions* or reportable conditions.

When selecting activities or programs for audit, we direct our efforts based on risk and opportunities to improve State government operations. Consequently, we prepare our performance audit reports on an exception basis.

AGENCY RESPONSES

Our audit report contains 3 findings and 3 corresponding recommendations. MDARD's preliminary response indicates that it agrees with all of the recommendations.

The agency preliminary response that follows each recommendation in our report was taken from the agency's written comments and oral discussion at the end of our audit fieldwork. Section 18.1462 of the *Michigan Compiled Laws* and the State of Michigan Financial Management Guide (Part VII, Chapter 4, Section 100) require an audited agency to develop a plan to comply with the recommendations and submit it within 60 days after release of the audit report to the Office of Internal Audit Services, State Budget Office. Within 30 days of receipt, the Office of Internal Audit Services is required to review the plan and either accept the plan as final or contact the agency to take additional steps to finalize the plan.

SUPPLEMENTAL INFORMATION

Our audit report includes supplemental information presented as Exhibits #1 and #2. The water quality test results in Exhibit #1 were a factor supporting our conclusion for the second audit objective. Our audit was not directed toward expressing a conclusion on the information presented in Exhibit #2.

*See glossary at end of report for definition.

GLOSSARY OF ABBREVIATIONS AND TERMS

Code of Federal Regulations (CFR)	The codification of the general and permanent rules published by the departments and agencies of the federal government.
DEQ	Department of Environmental Quality.
effectiveness	Success in achieving mission and goals.
FDD	Food and Dairy Division.
material condition	A matter that, in the auditor's judgment, is more severe than a reportable condition and could impair the ability of management to operate a program in an effective and efficient manner and/or could adversely affect the judgment of an interested person concerning the effectiveness and efficiency of the program.
maximum contaminant level	The maximum amount of a contaminant allowed in water set forth by the U.S. Food and Drug Administration in federal regulation 21 <i>CFR</i> 165.110.
MDARD	Michigan Department of Agriculture and Rural Development.
mg/L	milligrams per liter.
performance audit	An audit that provides findings or conclusions based on an evaluation of sufficient, appropriate evidence against criteria. Performance audits provide objective analysis to assist management and those charged with governance and oversight in using the information to improve program performance and operations, reduce costs, facilitate decision making by parties with responsibility to oversee or initiate corrective action, and contribute to public accountability.
reportable condition	A matter that, in the auditor's judgment, is less severe than a material condition and falls within any of the following categories: an opportunity for improvement within the context of the audit objectives; a deficiency in internal control that is significant within the context of the audit objectives; all instances of fraud; illegal acts unless they are inconsequential within the context of the audit objectives; significant violations of provisions of contracts or grant agreements; and significant abuse that has occurred or is likely to have occurred.

