

HB

378

Subject: RE: HB 378 - Food Safety Bill Hearing on Monday

Date: Mon, 23 Feb 2004 09:31:07 -0900

From: "Lesh, Melanie" <Melanie_Lesh@dec.state.ak.us>

To: 'Geraldine Mcintosh' <Geraldine_Mcintosh@Legis.state.ak.us>, 'Vanessa Tondini' <vanessa_tondini@legis.state.ak.us>

CC: "Ryan, Kristin J." <Kristin_Ryan@dec.state.ak.us>, "Lesh, Melanie" <Melanie_Lesh@dec.state.ak.us>

These are folks who will call into House Judiciary 2/23/04 1:00 p.m. on **HB 378** who are available for questions/testimony.

Testifiers/offnets:

Elise Hsieh, (pronounced chia) Assistant Attorney General, Department of Law (drafter)

Ed Sniffen, Assistant Attorney General, Consumer Protection Section, re: all the statutory reference changes re: enforcement of mislabeling/misbranding.

Michele Leffel, CHARR (can testify in favor).

Robin North, Alaska Food Safety Trainer, (can testify in favor).

Mike Halko, Bristol Bay Area Health Corp (can testify in favor). Not sure what number he will call in from - probably 842-3396

Ted Bradley, Alaska Marine Highway System

Melanie G. Lesh

Legislative Liaison

Department of Environmental Conservation

410 Willoughby Avenue

Juneau, Alaska 99801

Phone: 465-5290 Fax: 465-5070

-----Original Message-----

From: Ryan, Kristin J.

Sent: Monday, February 23, 2004 9:14 AM

To: Lesh, Melanie

Subject: FW: HB 378 - Food Safety Bill Hearing on Monday

HOUSE COMMITTEE REPORT

2.9.04

(7)

Date Referred to Committee: January 12, 2004

FURTHER REFERRALS: Judiciary

Date of Committee Action: 2/05/04

The HEALTH, EDUCATION AND SOCIAL SERVICES Committee considered:

HB 378

HOUSE BILL NO. 378

FOOD, DRUGS, COSMETICS, CERTAIN DEVICES

"An Act relating to the Alaska Food, Drug, and Cosmetic Act, including sales, advertising, certain devices, food donors, and food banks; making certain violations of organic food provisions and of the Alaska Food, Drug, and Cosmetic Act unfair methods of competition and unfair or deceptive acts or practices under certain of the state's unfair trade practices and consumer protection laws; and providing for an effective date."

Recommends it be replaced with [] HCS or [] CS for _____ (_____)

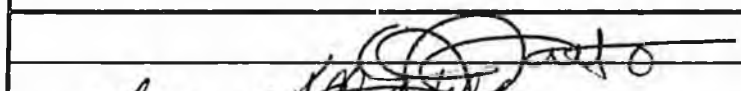
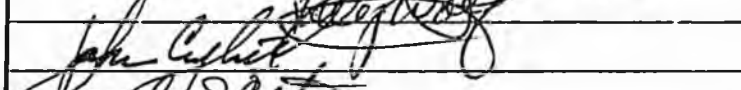
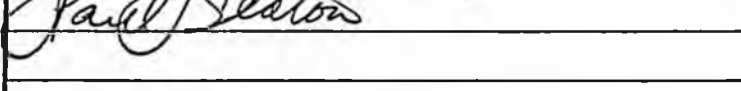
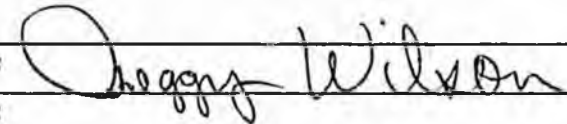
For Senate Bills with new title: [] Technical Title [] New Title: HCR _____ [] Same Title [] New Title

- [] attach amendments
- [] add new referral to _____ Committee
- [] Letter of Intent _____ Committee

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GOV
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REV
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UA

NEW FISCAL NOTES				
*Assigned by Chief Clerk's Office				
List by Dept(s):	*FN#	Fiscal	Indet.	Zero
LAW	1			✓
DEC	2	✓		

PREVIOUS FISCAL NOTES				
List by Dept(s):	FN#	Fiscal	Indet.	Zero

Signing with recommendations	Printed Last Name	DP	DNP	NR	AM
	GATTI	2	0	2	
	WOLF		✓		X
	SEATON	✓			✓
Chair: 	WILSON	✓			
Chair:					

AMENDMENT #1 - FAILED

OFFERED IN THE HOUSE
TO: HB 378

BY REPRESENTATIVE GARA

- 1 Page 5, following line 23:
2 Insert a new bill section to read:
3 **** Sec. 11.** AS 17.20 is amended by adding a new section to read:
4 **Sec. 17.20.355. Certification costs.** A person who has an employee who is
5 subject in the course of the employment to the certification requirements adopted by
6 the commissioner under AS 17.20.005(1)(D) shall pay the costs that are necessary for
7 the employee to meet the certification requirements. The employer may not require
8 the employee to reimburse the employer for these payments."
9
10 Renumber the following bill sections accordingly.

concept. A. to A#1:
by Gruenberg
shall not
req. DEC
"to do
anything"

by Brundage
Conceptual Amendment to H6378
WITHDRAWN

page 4 line 4 add

"or the Department of Health and social
services for those provisions it is responsible for
enforcing under AS 17.20.290 (c)."

Memorandum

DATE: November 7, 2000

TO: FOR THE RECORD

FROM: Michael Beller, M.D., M.P.H.
Medical Epidemiologist

THRU: Sue Anne Jenkerson, R.N.C., M.S.N., F.N.P.
Nurse Epidemiologist

FROM: Kim Mynes-Spink, R.N., B.S.N.
Nurse Epidemiologist

SUBJECT: Final Report - Escherichia coli O157:H7 outbreak-Kenai Peninsula

Introduction

On July 18, 2000, the microbiologist at Central Peninsula General Hospital in Soldotna reported four laboratory-diagnosed cases of Escherichia coli O157 infection and said other patients with diarrhea had been seen in the emergency department. An outbreak investigation was immediately begun. This report summarizes Interim Reports of July 20, 21, and 28 and presents additional information collected since the last Interim Report.

Methods

We interviewed persons living on or visiting the Kenai Peninsula in July who developed an acute gastrointestinal illness (diarrhea, abdominal cramping, or bloody diarrhea) or had a positive stool specimen for E. coli O157. Initially, subjects were interviewed because they presented to Central Peninsula Hospital with gastrointestinal symptoms. After notification of Kenai Peninsula physicians of the outbreak and news media coverage beginning on July 20, other ill persons contacted the Section of Epidemiology. A questionnaire was used for the interviews (Attachment 1).

Because the interviews suggested that the source of the outbreak was the Mad Moose restaurant in Sterling (see Results), we interviewed all workers there. We obtained

worker schedules and compared shifts with times and dates that ill patrons had eaten at the restaurant.

Stool specimens were collected from all restaurant workers (irrespective of illness status) and requested from ill persons identified during the interviews. Some ill persons did not submit specimens. Positive specimens from hospital laboratories were sent to the State Public Health Laboratory and the U.S. Centers for Disease Control and Prevention (CDC) for confirmation, complete identification, and pulsed field gel electrophoresis (PFGE), a type of "genetic fingerprinting." The enzymes used for the PFGE were XbaI and BlnI. PFGE also was performed on an Anchorage E. coli O157:H7 isolate from July 2000 and a Sterling isolate from September 2000. In order to examine isolates unrelated to the outbreak, PFGE was done on three E. coli O157:H7 isolates from sporadic Alaska cases during 1998.

On July 19, the Department of Environmental Conservation (DEC) inspected the implicated restaurant. Food samples, including ground beef and hamburger patties, were obtained and sent to the State Public Health Laboratory and cultured for E. coli O157. The next day, the DEC inspector used culture swabs to collect samples from a cutting board, a meat slicer, and kitchen surfaces. The swabs were sent to the DEC laboratory in Palmer and used as cleanliness indicators and for quality control at the laboratory.

On July 18, the U.S. Department of Agriculture issued a recall for ground beef contaminated with E. coli O157 that had been sold by an Anchorage meat supplier. We obtained information on the ground beef sold by the supplier and the sources of meat used by the restaurant. CDC compared the PFGE pattern of the E. coli O157 isolate from the recalled ground beef to the isolates from ill restaurant patrons and workers.

We obtained from the restaurant owner a list of 28 patrons that had eaten at the restaurant during July 6 to 9, 2000 and paid by check. They were interviewed about illness in their households.

On August 23, Dr. Michael Beller and Kim Mynes-Spink met with the restaurant owner to review our findings and answer questions. The owner was given information about E. coli O157:H7, graphs used in the investigation, and the PFGE results.

Results

In all, 58 persons were investigated who either had gastrointestinal illness or worked at the restaurant. Stools were collected from 39 of them, including all 12 restaurant workers. Since all persons with a positive stool culture had eaten at the Mad Moose 2 to 7 days before becoming ill and no other common exposures - restaurants, grocery stores, or social gatherings - were identified, we defined cases as follows:

1. A **confirmed case** was a person who within 8 days eating or working at the Mad Moose on or after July 1, 2000 either
 - had a stool culture positive for E. coli O157:H7, or

- met the clinical case definition (see below) **and** had eaten one or more meals at the restaurant with a person with a positive stool culture.
- 2. A **clinical case** was a person who ate or worked at the Mad Moose on or after July 1 and within 8 days had diarrhea, abdominal cramping or bloody diarrhea but did not have a positive stool culture.
- 3. A **secondary case** was a person with a stool culture positive for E. coli O157:H7 who developed acute gastrointestinal symptoms within 3 weeks of having contact with a household member who had eaten or worked at the Mad Moose.

There were 19 confirmed cases (16 patrons and three workers; all but two of which were laboratory confirmed), 10 clinical cases (nine patrons and one worker), and two secondary cases (both were siblings of a worker). This left 18 persons who reported being ill but had not eaten at the Mad Moose (five submitted stool for culture; all were negative) and nine employees who did not report having gastrointestinal symptoms and had negative stool cultures. All persons with E. coli O157:H7 infection in Alaska during April to August 2000 (except for an Anchorage resident with E. coli O157:H7 infection during June, see below) had either eaten or worked at the Mad Moose or lived with someone who had.

The most common symptoms experienced by cases were bloody diarrhea and abdominal cramping (Table 1). Cases ranged from 10 months to 73 years of age. Nearly 75% of the cases (23/31 or 74%) resided on the Kenai Peninsula; 12 in Kenai or Soldotna and 11 in Sterling. The remaining cases resided in Anchorage (n = 3), the State of Arizona (n = 3), and Wasilla (n = 2). For confirmed cases, 11 were male and eight were female; clinical cases included five males and four females; both secondary cases were male. Eleven cases were hospitalized; there were no deaths or serious sequelae, such as hemolytic uremic syndrome.

Among Mad Moose patrons, illness onset dates ranged from July 10 to July 24 (Figure 1). Patrons ate at the restaurant from July 7 to July 19 (Figure 2). The restaurant was closed on July 10, July 17, and July 20 to August 4. The mean interval between eating at the Mad Moose and onset of symptoms was 2.8 days (range: 2 – 7 days).

Among the 25 patron cases, none reported eating breakfast at the restaurant, 11 had lunch, 11 had dinner, and three had more than one lunch or dinner. Two were unsure of meal dates. No common food items were identified: nine had hamburgers, five had prime rib, three had club sandwiches, and one each had cashew salad, chef's salad, turkey sandwich, bacon-lettuce-tomato sandwich, and chicken fried steak (Table 2). Because patrons had difficulty recalling food items other than the main course, we did not ask them about salads, side dishes, or beverages.

Four restaurant workers reported having gastrointestinal symptoms during July, onsets were from July 11 to July 16 (Figure 2). Three of the four had positive stool cultures. The ill worker with a negative culture had illness onset on July 11 but did not submit a stool specimen until July 31. Employees had meal privileges at the restaurant and ill workers had eaten multiple meals.

Nine of the E. coli O157:H7 isolates were submitted to CDC; all were confirmed. The State Public Health Laboratory conducted PFGE on isolates from 17 confirmed cases, an isolate from an Anchorage infection in July 2000, an isolate from a Sterling infection in September 2000, and three unrelated isolates from 1998. Twelve patron isolates and three employee isolates had an indistinguishable PFGE pattern, which was termed the "outbreak pattern." Two of the outbreak pattern isolates were submitted to the State Public Health Laboratory by an Arizona laboratory since the patients, both patrons of the Mad Moose, had returned home to Arizona by the time of illness onset. Two patron isolates were indistinguishable from the outbreak pattern with the BlnI enzyme but had a one band difference with XbaI enzyme. The three isolates from previous infections and the July Anchorage isolate had PFGE patterns markedly different from the outbreak pattern (the ill Anchorage resident had not eaten at the restaurant). The September Sterling isolate was similar to the outbreak pattern though the patient had not eaten at the restaurant (see attachment).

Findings from the DEC inspection conducted on July 19 were: inadequate separation of cooked meat, uncooked meat and other foods; use of a cutting board that could not be cleaned thoroughly; inappropriate cooling process for prime rib; and inadequate hand washing between handling uncooked meat and other foods.

All 13 food samples taken on July 19 tested negative for E. coli O157:H7. Results from the culturette swabs varied from common organisms such as Streptococcus to Enterobacter cloacae; no E. coli O157:H7 was identified.

A small amount of ground beef used by the restaurant was purchased from a major retail store in Soldotna. Most of the ground beef served during the outbreak was purchased from a supplier on the Kenai Peninsula. From July 6 to July 18 the restaurant received three 80-pound shipments. The supplier had purchased meat from an Anchorage distributor. This distributor had sold ground beef to multiple suppliers including the Kenai Peninsula supplier and an Anchorage supplier that had been the subject of the USDA recall.

The PFGE pattern of the E. coli O157:H7 isolate obtained by USDA from the recalled ground beef was different than the outbreak pattern. The restaurant owner denied purchasing any meat from the Anchorage supplier. The sausage and bacon served during breakfast were purchased from a different supplier on the Kenai Peninsula. The restaurant also obtained steak, prime rib, seafood, produce and miscellaneous items from this supplier.

We completed telephone interviews with 29 residents from 14 households on the list of restaurant patrons that had paid by check during July 6 to July 9. Five patrons had breakfast, five had lunch, and 21 had dinner; two of the lunch patrons also had breakfast during July 6 to July 9 (Table 3). Four reported having diarrhea 2 to 7 days after eating at the restaurant, all four reported having lunch or dinner at the restaurant on July 7 or July 9. The restaurant owner said 150 to 200 patrons ate lunch or dinner each day during July.

By applying the attack rate for lunch and dinner patrons in the survey (4/26 or 15%) to the estimated 1,500 to 2,000 lunch or dinner patrons served during July 7 to 19, we estimated at 225 to 300 persons may have been ill after eating at the restaurant.

All three workers with laboratory confirmed infection worked during the outbreak period. The other ill worker (with a negative stool culture) last worked on July 8 and became ill on July 11. All employees were involved in some food handling, preparation, or serving. There was no individual work schedule that matched the dates that ill patrons ate at the restaurant.

After the restaurant re-opened on August 4, one case of E. coli O157:H7 was reported from Sterling through the end of September. This case was not linked to the implicated restaurant (see attachment). There were seven other E. coli O157:H7 infections reported in Alaska between August 4 and September 30: five in Anchorage and one each in Seward and Fairbanks. None of these were linked to the restaurant

Discussion

Alaska has had very few E. coli O157:H7 infections reported (an average of 6.3 per year during 1997-1999), so the occurrence of almost 20 cases in less than a month is very unusual. The facts that all 19 laboratory confirmed cases either ate or worked at the Mad Moose and that 15 had an identical PFGE pattern were overwhelming evidence of a link between illness and the restaurant. The conclusion is further supported by the:

- absence of any other common exposure despite careful and extensive questioning,
- presence of serious sanitation deficiencies at the restaurant,
- mean interval between eating at the restaurant and illness onset was the same as the established incubation period (3 to 4 days, range 2 to 8 days) for E. coli O157:H7 infection, and
- observation that the outbreak stopped when the restaurant closed.

Although the epidemiologic and laboratory evidence demonstrated that the restaurant was the source of the outbreak, the investigation did not implicate any particular food item, food handler, or practice. This does not alter the conclusion that the outbreak came from the restaurant. Nearly all the patrons who became ill after eating on July 7, 9, and 11 had eaten hamburgers or prime rib. Given the well-established link between beef and E. coli O157:H7 and DEC's observation of food handling deficiencies, it is possible that the initial patrons and employees became ill after eating undercooked meat. Subsequently, infected restaurant workers could have been the source of illness among patrons who ate during July 13 to 19. A ground beef recall which occurred at the same time as the outbreak had no connection to the outbreak.

Food and kitchen surface samples taken on July 19 and 20 tested negative for E. coli O157:H7. These samples were collected 10 to 12 days after the outbreak started and were not from the same food shipments the ill patrons ate. Environmental swabs were collected after the restaurant closed and cleaning had occurred. Clearly, the culture results do not mean that meat served earlier did not contain E. coli O157:H7, that kitchen

surfaces were not contaminated, or that foods were not cross-contaminated with E. coli O157:H7 from meat.

Humans generally excrete E. coli O157:H7 for 1 or 2 weeks after being infected. Therefore, some of the nine workers who had negative stool cultures in mid- to late-July could have been culture positive earlier in the month. In particular, the worker with illness onset on July 11 could have had E. coli O157:H7 infection despite a negative culture of a stool collected on July 31.

Because the infectious dose is low, E. coli O157:H7 is readily transmitted from one person to another. Since the three workers with positive stool cultures worked while ill, a worker could have passed infection to patrons. We did not find a link between employee schedules and when patrons dined. However, the restaurant owner said the work schedule we were given was not the actual schedule (employees were allowed to trade days off or shifts). We requested a copy of the actual work schedule, but the owner did not provide one.

This outbreak was probably larger than the 31 cases identified. Investigation suggested that 15% of lunch and dinner patrons during the outbreak, or 225 to 300 persons, might have been sickened. Since some persons with E. coli O157:H7 infection have relatively mild symptoms, and many persons with diarrhea do not obtain medical care, we suspect that the true number of cases was substantially larger than the number of confirmed and clinical cases. The restaurant was in a community with a large influx of out-of-state tourists and additional cases may have returned home before becoming ill.

In conclusion, our investigation traced an E. coli O157:H7 outbreak to a restaurant. The restaurant was closed and the outbreak stopped. DEC worked with the owner and employees to correct all deficiencies before the restaurant re-opened. Because the source of the outbreak was quickly identified, disease transmission was stopped even though the precise mechanism of spread was not determined.

Acknowledgments: Janet Gleason and Lenore Winkopp at Central Peninsula Hospital were extremely helpful in providing up-to-date information as the outbreak progressed. Patty Little, PHN at the Kenai Health Center quickly and efficiently completed interviews and collected stool specimens.

Attachments: Interim Reports
Memo to the Record, Escherichia coli O157 – Sterling

CC: Brad Tufto, DEC
Jerry Ferrington, DEC
Cory Willis, DEC
Janet Gleason, Central Peninsula Hospital
Patty Little, Kenai Health Center

Alaska State Legislature

Co-Chair
House Finance Committee
Subcommittee Chair
Environmental Conservation
Courts



Representative William K. Williams

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Fax (907) 225-8546

MEMORANDUM

DATE: February 6, 2004

TO: Representative Lesil McGuire, Chair
House Judiciary Committee

FROM: Representative Bill Williams, Co-Chair
House Finance Committee

RE: Hearing Request, HB 378

*Geraldine McIntosh
for WKW*

I respectfully request the scheduling of HB 378, "An Act Relating to the Alaska Food, Drug, and Cosmetic Act" at your earliest convenience. Attached a copy of the Sponsor Statement and the most recent version of the bill.

If you have any questions, please contact Geraldine McIntosh of my staff at 465-3424.

Thank you for your consideration.

Alaska State Legislature
House Finance Committee

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HB 378

Sponsor Statement

HB 378 amends provisions in Title 17 relating to the powers of the Commissioner of the Department of Environmental Conservation (DEC) relating to food offered or sold to the public. The bill makes it possible for DEC to require food-handling operators to become trained and certified and assess fines. Both of these capacities are needed as part of the new food safety paradigm - Active Managerial Control. In addition, the bill defines a violation of labeling or advertising as a violation of the unfair trade and consumer protection provisions.

Currently, AS 17.20.005 allows the Commissioner of DEC to issue orders, regulations, permits, embargoes, and quarantines. This includes inspection, sanitation standards, food handling methods, and labeling. Under this bill, the Commissioner of DEC will have additional authority to ensure knowledge of food safety and sanitation by individuals who handle or prepare food for the public, and persons who supervise or employ those individuals. This bill also authorizes DEC to impose a civil fine for a violation of the Alaska Food, Drug, and Cosmetic Act.

HB 378 also clarifies that a violation of the label or advertisement provisions in AS 17.20, or a violation of the representation requirement in AS 17.00 is an unfair or deceptive trade practice under Alaska's Statutes. This will allow the Attorney General's office to investigate labeling violations that are not food safety or sanitation concerns.

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Geraldine McIntosh
Staff

The 23rd Alaska State Legislature

Representative Bill Williams

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Food, Drugs, Cosmetics, Certain Devices

Sponsor Statement for HB 378

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Last Updated: February 2, 2004

Geraldine McIntosh
Legislative Aide 465-3424
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"An Act relating to the Alaska Food, Drug, and Cosmetic Act, including sales, advertising, certain devices, food donors, and food banks; making certain violations of organic food provisions and of the Alaska Food, Drug, and Cosmetic Act unfair methods of competition and unfair or deceptive acts or practices under certain of the state's unfair trade practices and consumer protection laws; and providing for an effective date."

"The bill makes it possible for DEC to require food-handling operators to become trained and certified and assess fines."

- Rep. Williams

HB 378 amends provisions in Title 17 relating to the powers of the Commissioner of the Department of Environmental Conservation (DEC) relating to food offered or sold to the public. The bill makes it possible for DEC to require food-handling operators to become trained and certified and assess fines. Both of these capacities are needed as part of the new food safety paradigm - Active Managerial Control. In addition, the bill defines a violation of labeling or advertising as a violation of the unfair trade and consumer protection provisions.

Currently, AS 17.20.005 allows the Commissioner of DEC to issue orders, regulations, permits, embargoes, and quarantines. This includes inspection, sanitation standards, food handling methods, and labeling. Under this bill, the Commissioner of DEC will have additional authority to ensure knowledge of food safety and sanitation by

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individuals who handle or prepare food for the public, and persons who supervise or employ those individuals. This bill also authorizes DEC to impose a civil fine for a violation of the Alaska Food, Drug, and Cosmetic Act.

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###

Attachments:

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13 KB

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House Bill 378 Testimony

Kristin Ryan - Director, Division of Environmental Health

- Restaurant industry sales account for 4 percent of the U.S. gross national product. According to the National Restaurant Association, Alaska saw sales of \$878 million in 2003, and is projected to see sales of \$922 million in 2004 (a 5% increase).
- Nationwide, the industry employs 12 million people, the nation's largest private-sector employer. In Alaska the numbers vary by season but averages to about 20,000 or 3% of the population (total pop 626,932).
- In 2000, an E. Coli outbreak at a Kenai restaurant resulted in 31 known sick Alaskans and an estimated 300 more unknown. The cause was infected workers, poor hand washing, food temperature control and cross contamination - All things easily avoided by a knowledgeable workforce. The operation permanently closed as a result.

Alaska needs a more effective food safety system - a system that ensures operators and staff are knowledgeable about food safety and accountable for controlling practices and procedures that contribute to foodborne illness. A system that sets reasonable standards, can be equitably implemented in both urban and rural settings, and does not rely on an infrequent government inspection to determine if standards are being met on a day-to-day basis.

- **Certification is a necessary part of an effective food safety system.**
- **Enforcement tools are necessary to promote compliance.**
- **Certification and enforcement are key components of Alaska's new Food Safety protection system called Active Managerial Control.**

1. Certification is a necessary part of an effective food safety system.

- a. Government food protection programs across the country are grappling with diminishing resources and ineffective delivery systems. Relying on government inspections as the primary tool to ensure high sanitary standards is no longer considered an effective method to ensure food offered or sold to the public is safe. The premise that inspections can improve sanitation of restaurants is flawed. Alaska has never been able to inspect frequently enough to truly protect public health. A national trend toward a more effective food safety program makes it a food worker's responsibility to practice established safe food handling skills 365 days a year, and prove it through certification and testing.
- b. A national study found restaurants for which managers were required to attend a training and certification program demonstrated significantly improved sanitation practices that were sustained over a two-year follow-up period.

- c. Alaska's food permit holders were asked what they needed for a safe food handling system. Out of 321 respondents 89% stated mandatory food manager certification was necessary and 82% believed mandatory food handler training was also necessary.
- d. Forty-one States or local governments have mandated certification requirements. Most remaining jurisdictions have voluntary programs like Alaska's current program.
- e. It is a mark of professionalism to meet criteria determined by one's peers. Lawyers take the bar examination, doctors pass boards, and public accountants become CPAs. The process of certification and demonstrated knowledge raises professional esteem and expectations.

2. Enforcement tools are necessary to promote compliance.

- a. Issuing a notice of violation, closing a facility, or pursuing criminal prosecution are currently the only enforcement tools DEC can use to promote compliance. Closing a facility is only appropriate when a serious health threat exists, and there are practical, procedural, and economic constraints to pursuing criminal prosecution for regulatory violations. Having the capacity to issue appropriate fines for violations that are significant or repeat violations provides a more reasonable, efficient, and effective mechanism to ensure food offered or sold to the public is safe and deter subsequent violations.
- b. Some say that the threat of consumer lawsuits is adequate motivation for operators to serve safe food. However, many foodborne illnesses go unreported and cannot be attributed to a specific eating establishment. The median reported cases were 25:1.

3. Certification and enforcement are key components of Alaska's new Food Safety protection system called Active Managerial Control.

Each individual in the food chain from farmer to processor to retailer to consumer has some responsibility for food safety. The ultimate responsibility at the retail level lies not with the regulator but with the food service operators.

What makes an effective food safety system or regulatory program?

- a. Unambiguous statutory authority. Alaska has a solid statutory foundation to ensure sanitary practices are used in the operation of a food handling establishment.
- b. Documented basis for concern.
 - 1. Centers for Disease Control estimates 76 million illnesses, 325,000 hospitalizations and 5,000 deaths a year caused by foodborne illness
 - 2. Foodborne illness can be traced to several sources--61% is traced to the foodservice industry, 32% to homes and 7% to food processing plants.

- c. Protective standards - With nearly 100 years of food safety regulation experience in the U.S. we know that the 5 risk factors that must be controlled are: food from unsafe sources, inadequate cooking, inadequate holding, contaminated equipment and poor personal hygiene.
- d. Rational regulatory scheme. 32 Alaska food safety experts (Food Safety and Sanitation staff) have reviewed how jurisdictions and industry ensure food safety in other states and developed Alaska's new regulatory scheme called Active Managerial Control. As the name implies, responsibility for food safety has been clearly placed on operators. It consists of food service workers that are knowledgeable about the causes of foodborne illness and practices to control them, written standard operating procedures and self-audits, and DEC enforcement implemented through on-sight inspections and record audits. HB 378 is needed to make the proposed rational regulatory scheme of AMC possible.
- e. Documented compliance. AMC incorporates various ways for operators to document and DEC health officers to verify compliance.
- f. Enforcement. Flexible mechanisms are needed to promote compliance through appropriate actions that prevent and deter rather than ineffective mechanisms that only react and punish.

- **Certification is a necessary part of an effective food safety system.**
- **Enforcement tools are necessary to promote compliance.**
- **Certification and enforcement are key components of Alaska's new Food Safety protection system called Active Managerial Control.**



Knowledgeable Workforce

Trained Workers

Certified Managers

Managing Risks

Quarterly Self Assessments

Standard Operating Procedures:

- Cleaning & Sanitizing
- Handwashing
- Employee Health
- Receiving and Storage
- Risk Factor related SOPs

Enforcement

Record Audits

Risk Based Inspections

Enforcement Actions

Dirty dining?
**'Dateline' hidden
cameras investigate
cleanliness of America's
top 10 fast food chains**

Fast food: It's served fast and you eat it fast, maybe too fast to notice the restaurant is a little dirty. The fact is that no one has ever done a national survey looking at the cleanliness of fast food chains — until now. Recently, we took our Dateline cameras undercover for the first-ever investigation of whether America's top 10 fast food chains are clean and safe. How did your favorite restaurant do? We're a nation fueled by fast food: burgers and fries, tacos, fried chicken. It's hot, tasty and easy. And with millions and millions of meals sold every day, most of us just assume it's all clean and safe. But when it's not, it can be devastating.

After eating at this McDonalds in Erwin, Tenn., last March, one hundred people became violently ill. Some ended up in the hospital, dehydrated and even hallucinating. The Centers for Disease Control says sick restaurant employees very likely contaminated food with a virus, although McDonald's disputes that.

Meanwhile, after eating at a KFC in Colorado, Gianni Velotta was infected with a dangerous salmonella bacteria. His mother says he almost died.

Natalie Velotta: "His kidneys weren't working. I mean, there's just no words to explain how bad it actually was."

How do your favorite restaurants rate?

Was there any way to prevent it? Well, had Natalie Velotta checked, she'd have learned health inspectors had cited and fined that KFC just a few months earlier.

Velotta: "If I would have known that they had several health violations, I would not have eaten there."

But who has time to check health inspection reports before they go to a fast food restaurant? Virtually no one, so Dateline decided to do it.

The biggest 10 chains have 75,000 restaurants. We couldn't look at all of them, so we hired a survey company to choose a sample, 100 restaurants from each chain, 1,000 in all, spanning 38 states.

We then collected and examined local health inspection reports for the last year and a half on each of those 1,000 restaurants. Some were inspected just once, some more often during that period.

In a first of its kind national investigation, Dateline is going to use these health inspection reports to find out which fast food chains in our survey are the cleanest and the dirtiest. What we found may do more than surprise you. Some of the horror stories in Dateline's dirty dining survey just might turn your stomach.

In a Chicago, in a Wendy's, inspectors found dead rodent decomposing on a rat trap. At a California Taco Bell, someone bit into a taco, only to find chewing gum. An inspector in Texas found a worm in a Wendy's salad. At a Hardee's in Florida, a customer was handed a cup of soda with blood dripping from it. There was blood on her change as well.

The list goes on. A cockroach in someone's soda, a sharp metal object in a man's sandwich. But as disgusting as those things are, they are rare. Experts say the things you can't see can be even more hazardous.

So what can be done about all this? Well, health inspectors tell us it's not that easy to just close down a restaurant, and they say their power is limited when it comes to even imposing heavy fines. What they can do is cite restaurants for what is known as a hazardous or critical violation.

Caroline Smith-Dewaal is with the Center for Science in the Public Interest, a food safety watchdog group.

Smith-Dewaal: "A critical violation is something that happens in a restaurant that may result in the food becoming contaminated."

Lea Thompson: "By definition, is a critical violation something that could make you sick?"

Smith-Dewaal: "Yes."

Critical violations are a benchmark for judging a restaurant's cleanliness. Most food regulations mandate they be corrected immediately, and they are the only type of violations we counted in our survey. They include things like handling ready-to-eat food with bare hands or unwashed hands, undercooked meat, improper food holding temperatures, sick employees preparing food, and a host of other potentially

hazardous problems.

What may shock you is just how many restaurants had critical violations. More than sixty percent of all fast food restaurants in our sample had at least one critical violation in the last year and a half.

How many total violations did each chain have? Here comes Dateline's dirty dining survey — it's a top 10 list where no fast food restaurant wants to come in number one:

10: TACO BELL

The 100 Taco Bells we sampled had the fewest total critical violations, 91, making it the best performer in our survey. But it was not without problems. Recurring violations included dirty food preparation counters and rodent droppings.

9. MCDONALD'S

The golden arches, the 100 McDonald's we looked at came in with a total of 136 critical violations. Some didn't have a trained and certified food handler on the job, required by law in many states.

Thompson: "It's that important?"

Smith-Dewaal: "Absolutely. We can't have food prepared by people who don't know that you can't combine raw meat with cooked meat, with people who don't understand the importance of proper temperatures in food preparation."

8. KFC

The 100 KFCs we sampled tallied up 157 critical violations, and two thirds of the "finger lickin' good" restaurants had at least one critical violation. Remember, it was at a KFC, the Health Department says, little Gianni Velotta picked up salmonella poisoning last year. We've now learned that another child was also sickened there, and the same restaurant has since been cited for three more critical violations.

While the Velotta's have settled a lawsuit against the restaurant, a lawyer for the owner of the franchise contends the salmonella cases did not originate there.

7. SUBWAY

The 100 Subways we looked at totaled 160 critical violations. A recurring problem at the sandwich chain was improper food holding temperatures.

Thompson: "What does that mean?"

Smith-Dewaal: "That means that bacteria in the food that's already cooked can start to grow, and it can reach levels that can cause serious illness for someone who consumes it."

6. JACK IN THE BOX

The 100 Jack in the Box restaurants had a total of 164 critical violations. A Ventura, Calif., Jack in the Box was a trouble spot. It had several customer complaints of food borne illness.

5. DAIRY QUEEN

The 100 Dairy Queens we examined totaled 184 total critical violations. One Dairy Queen in Hampton, Va., rang up a number of critical violations last summer for grime, debris, and an inaccurate thermometer.

When Dateline went back recently to take a look, the restaurant invited us in, and showed it had fixed the problem.

4. HARDEES

The 100 Hardee's tallied 206 critical violations. Again and again inspectors cited the presence of insects and rodents.

Smith-Dewaal: "Rodents and roaches are gross. But more importantly, they can also spread germs from food to food, and carry germs into a restaurant."

Last May, one restaurant was cited for not having soap in the employee's sink. Yet, inspectors found employees handling ready-to-eat food with their bare hands.

3. WENDY'S

100 Wendy's had 206 critical violations. That's the same as Hardees, but more Wendy's restaurants had violations. So Wendy's is number three in our Dateline dirty dining survey.

At a Wendy's in Mesa, Ariz., inspectors noted repeated problems with food holding temperatures, mice droppings on the shelves, bare hand food contact, and one food borne illness complaint.

2. ARBY'S

The 100 Arby's had 210 critical violations. The roast beef specialists had recurring violations for improper hand-washing and employees handling ready-to-eat foods with their bare hands.

Smith-Dewaal: And clearly, if the person isn't washing their hands or using other sanitation practices, they can really make people very sick.

1. BURGER KING

So which fast food chain finished number one on Dateline's dirty dining list? It's Burger King. The 100 Burger Kings we sampled rang up a whopping 241 total critical violations. Health inspectors cited a Virginia Burger King for 14 separate critical violations: employees not washing their hands, uncovered food in the fridge, grime and debris found on this ice chute, and on the drink machine at the drive-thru window. We observed one employee scooping ice into a cup with his bare hands, an apparent critical violation.

SO WHAT'S THE BIG PICTURE?

The 1,000 restaurants we sampled totaled 1,755 critical violations, and 613 restaurants were cited at least once. That's more than 60 percent with problems inspectors consider potentially hazardous to your health.

Still, in an industry where millions of meals are served...

Thompson: "Is it unrealistic to expect a fast food restaurant to come up with a clean bill of health every single time an inspector walks in the door?"

Smith-Dewaal: "The government inspector is the last checkpoint. The restaurant itself should be doing inspections and checking for critical violations every day. They shouldn't wait for a government inspector to tell them they're doing it wrong."

Steve Grover of the National Restaurant Association represents fast food restaurants. He's a former health inspector himself.

Thompson: "Does Dateline's survey concern you?"

Steve Grover: "It concerns me. I do not find critical violations acceptable."

Thompson: "Why are they there in the first place?"

Grover: "Because no one's perfect. I tell the executives every day, 99.9 percent is not good enough, when it comes to food safety."

Thompson: "What about 60 percent?"

Grover: "Sixty percent is not good enough when it comes to food safety."

Grover argues as long as critical violations are being corrected promptly, then the system is working. Inspectors are doing their job, and the restaurants are following the advice of the inspectors as they come through.

Most fast food restaurants are owned by individuals, but most chains say they inspect every restaurant that has their name on it.

In a letter to Dateline, Burger King says it is "Extremely disappointed" by (the) findings... We want to assure our guests we will quickly investigate... and take immediate and appropriate actions..." The president of Wendy's writes, "one critical violation on a health inspection report is one too many." And Hardees says, "We must always do better. Any critical deficiency is unacceptable - which is why we address them immediately." McDonald's says "No one cares more about operating clean, safe restaurants than McDonald's."

All are unanimous in agreeing with KFC that "Food safety is our number one priority." The Velottas, whose little boy became almost died, hope that's true.

Velotta: "Every single time I go to a fast food restaurant, there's that doubt in the back of my mind that they could get sick. Every single time."

Audits and Inspections

Audits

- ▶ New and existing establishments will initially be required to submit their SOPs, records, and self-inspections for review.
- ▶ Annually, and as part of the permit review process, a percentage of randomly selected establishments will be required to submit their self-inspections and records.

Inspections

- ▶ On-site evaluations of establishments will be conducted to determine their control of risk factors, to review SOPs and how they are implemented, and to audit required records and self-inspections.
- ▶ Enforcement actions, including administrative fines, may be initiated for risk factors that are not being controlled, imminent health hazards and other serious violations of the regulations.

Implementing the New System

Target Schedule



- ▶ Public Notice Food Code Spring 04
- ▶ Revisions Adopted Fall 04
- ▶ CFPM Required Fall 04
- ▶ Food Worker Training Fall 04
- ▶ AMC Workshops Fall 04
- ▶ AMC Required Fall 05

Elements of this new food safety system will be included in draft revisions to the Food Code (18 AAC 31). Food Establishment operators are encouraged to comment and will be directly notified when the draft regulations go out for public notice.

Your input is important, and can improve the regulations. Every comment will be considered, and changes may be made based on the comments received.

For more information visit our website:

www.state.ak.us/dec/deh/



Food Safety & Sanitation

Active Managerial Control: Improving Alaska's Food Safety System



Active Managerial Control is a comprehensive food safety system. It includes operators and staff who are knowledgeable about food safety issues, and are responsible for controlling practices and procedures that contribute to foodborne illness. It can be implemented in both urban and remote settings.

This new system offers greater assurance that safe food is served throughout Alaska.

Alaska Department of Environmental Conservation
Division of Environmental Health
Food Safety and Sanitation Program
555 Cordova Street
Anchorage, AK 99501
(907) 269-7501 FAX (907) 269-7510

Elements of "Active Managerial Control"

Elements of Alaska's Food Safety System include trained food workers, standard operating procedures, monitoring and recordkeeping of certain risk factors, self-inspections, audits, and field evaluations. The details of these elements are explained below.

1. Training

- ▶ Establishments that serve unpackaged food will need to have a Certified Food Protection Manager (CFPM). She/he must pass a nationally recognized exam to become certified.
- ▶ All food workers must have food safety training and pass an exam.
- ▶ Many options will be available for both manager and food worker training, including self-study, online, and classroom training.

2. Written SOPs (Standard Operating Procedures)

Establishments must have SOPs that describe their policies on,

- ▶ proper handwashing,
- ▶ employee health,
- ▶ training,
- ▶ food sources,
- ▶ receiving and storage,
- ▶ chemical use and storage, and
- ▶ sanitation.

3. **SOPS, monitoring, and recordkeeping** will also be required, where applicable, for the following:

- ▶ hot and cold holding
- ▶ cooking,
- ▶ cooling,
- ▶ reheating, and
- ▶ handling ready-to-eat food.

4. Food Safety Checks

- ▶ Regular food safety checks, conducted by the operator, will help verify that the establishment's procedures, and good retail practices are being followed, and any required records are maintained.

The 5 Risk Factors for Foodborne Illness

Unsafe Holding Temperatures
Inadequate Cooking
Contaminated Equipment
Food from Unsafe Sources
Poor Personal Hygiene

Food Safety and Sanitation Program: Operator Assistance

DEC will hold workshops and provide training to help operators understand and implement Active Managerial Control. In addition, FSS plans to:

Provide Food Safety Training Opportunities

- ▶ Publish a list of CFPM Training Courses and Exams.
- ▶ Conduct Train the Trainer courses for employers and others who want to provide food worker employee training.
- ▶ Offer food worker training, testing, and certification online.
- ▶ Provide free training materials online and in print.

Provide Model SOPs and Forms

- ▶ Publish a Compliance Manual which will include permit applications, plan review requirements, instructions on identifying processes and risk factors, templates for writing customized SOPs, and example forms for recordkeeping and self-inspections. It will be available online and in print.
- ▶ Publish a Resource Manual to help operators implement their active managerial control system. It will include procedures for controlling risk factors, examples of policies, reproducible signs, and other information.

FISCAL NOTE

STATE OF ALASKA
2004 LEGISLATIVE SESSION

Fiscal Note Number: 1
 Bill Version: HB 378
 (H) Publish Date: 2/9/04

Revision Date/Time (Note if correction): _____ Dept. Affected: LAW
 Title "An Act relating to the Alaska Food, Drug, RDU Civil
and Cosmetic Act, including sales, advertising..." Component Environmental
 Sponsor House Finance
 Requester House Health, Education and Social Services Component No. _____

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Personal Services						
Travel						
Contractual						
Supplies						
Equipment						
Land & Structures						
Grants & Claims						
Miscellaneous						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0

CAPITAL EXPENDITURES						
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CHANGE IN REVENUES ()						
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FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts						
1003 GF Match						
1004 GF						
1005 GF/Program Receipts						
1037 GF/Mental Health						
Other (Specify Type--Do not abbreviate)						
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2004) cost: 0.0
 Mark this box (X) if funding for this bill is included in the Governor's FY 2005 budget proposal:

POSITIONS

Full-time						
Part-time						
Temporary						

ANALYSIS: (Attach a separate page if necessary)

This bill amends AS 17.20.005 by adding a requirement that training, testing and certification be required for individuals who handle or prepare food, their supervisors, and their employers to ensure knowledge of food safety and sanitation. It also broadens the potential penalties and fines that may be imposed on anyone who violates one of the prohibited acts under the Food, Drug and Cosmetics Act but provides certain exceptions, under certain circumstances for disseminators of false advertising, and for donors of food to a food bank and to food banks themselves. The bill also gives concurrent jurisdiction to the Attorney General to act against violators of this revised statute.

Passage of this legislation will have a negligible fiscal impact on the Department of Law.

Prepared by: Kathryn A. Daughhete, Director Phone 465-3673
 Division Administrative Services Date/Time 2/2/04 1:13 PM
 Approved by: Kathryn Daughhete for Gregg D. Renkes, Attorney General Date 2/2/2004
 Agency Department of Law

FISCAL NOTE

STATE OF ALASKA
2004 LEGISLATIVE SESSION

Fiscal Note Number: HB378-EC-EH-1-14-04

Bill Version: _____

() Publish Date: _____

Revision Date/Time (Note if correction):
Title An Act Relating to Food, Drug and Cosmetics

Dept. Affected: Environmental Conservation
RDU Environmental Health
Component Food Safety and Sanitation

Sponsor Representative Bill Williams
Requester _____

Component No. 2343

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

OPERATING EXPENDITURES	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
Personal Services	106.7	106.7	106.7	106.7	106.7	106.7
Travel	5.0	5.0	5.0	5.0	5.0	5.0
Contractual	13.2	13.2	13.2	13.2	13.2	13.2
Supplies	72.0	2.0	2.0	2.0	2.0	2.0
Equipment	13.8	2.0	2.0	2.0	2.0	2.0
Land & Structures	0.0	0.0	0.0	0.0	0.0	0.0
Grants & Claims	0.0	0.0	0.0	0.0	0.0	0.0
Miscellaneous	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL OPERATING	210.7	128.9	128.9	128.9	128.9	128.9

CAPITAL EXPENDITURES						
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CHANGE IN REVENUES (1005/1156)	80.0	157.0	77.0	157.0	157.0	77.0
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FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts	0.0	0.0	0.0	0.0	0.0	0.0
1003 GF Match	0.0	0.0	0.0	0.0	0.0	0.0
1004 GF	0.0	0.0	0.0	0.0	0.0	0.0
1005 GF/Program Receipts	0.0	0.0	0.0	0.0	0.0	0.0
1037 GF/Mental Health	0.0	0.0	0.0	0.0	0.0	0.0
1156 Receipt Supported Services	210.7	128.9	128.9	128.9	128.9	128.9
TOTAL	210.7	128.9	128.9	128.9	128.9	128.9

Estimate of any current year (FY2004) cost: 0.0

Mark this box (X) if funding for this bill is included in the Governor's FY 2005 budget proposal:

POSITIONS

Full-time	2	2	2	2	2	2
Part-time	0	0	0	0	0	0
Temporary	0	0	0	0	0	0

ANALYSIS: (Attach a separate page if necessary)

See Attached

Prepared by: Kristin Ryan, Director
Division Division of Environmental Health
Approved by: *Kristin Ryan*
Agency Department of Environmental Conservation

Phone 269-7645
Date/Time 1/14/04 12:22 PM
Date 1/14/2004

FISCAL NOTE

STATE OF ALASKA
2004 LEGISLATIVE SESSION

BILL NO. HB378-EC-EH-1-14-04

ANALYSIS

This bill authorizes the department to implement key elements of the new food safety program called - Active Managerial Control (AMC). This includes certification requirements for food service managers, separate food worker certification and testing, and authority to issue civil fines.

REVENUES

Food Worker Certification: Regulations will be implemented that require food workers to pass an exam administered by the department. A \$10.00 fee will be assessed for a three-year certification with a \$10.00 fee for each re-certification. There are approximately 16,000 food workers employed in the state.

- FY2005 – Half of the food workers will be certified in the first year of implementation producing \$80.0 in receipts. (There is a one-year grace period in effect that extends into FY2006).
- FY2006 – The other half of food workers will be certified plus 45% in new certifications representing estimated industry turnover for seasonal workers generating revenue estimated at \$152.0.
- FY2007 – Third year revenue is from turnover certification only.

Revenues continue in this pattern with a three-year re-certification cycle.

Civil Fines: Revenue projections include a minimal amount for civil fines at a rate of \$5.0 per year. The department will impose fines for failure to comply with the food safety system requirements or repeat or serious food safety violations. Food establishments will have a one year grace period for the necessary training and to implement the AMC system. Revenue from fines will not begin until after the grace period has expired (FY2006 or later) and are, at this point, difficult to estimate.

OPERATING COSTS

Personal Services: An Environmental Health Technician, will track compliance, deposit payments, issue certifications, and distribute training materials. An Environmental Health Officer will supervise Train-the-Trainer instruction on the requirements for food worker training and will coordinate with state and national providers of training for the Certified Food Protection Manager (CFPM) certification requirement in conjunction with state proctored exams.

Travel: Cost of conducting training, audits and to provide technical assistance.

Contractual: Funding for maintenance and support of the certification system and basic position support costs.

Supplies: Costs include a first year, one-time expenditure of \$70.0 for the purchase and implementation of a Food Safety System (software) that will provide food worker training and testing on-line and in multiple languages. Training and certification will be available in remote as well as urban areas, and to workers for whom English is not the primary language.

Equipment: Standard equipment purchases in the first year with ongoing maintenance costs.

FUNDING

Receipts from annual food establishment permit fee collections will be used to fund AMC activities.

Personal Services New Position Detail

Department of Environmental Conservation

Scenario: A Scenario for FY2005 Fiscal Notes (3605)
 Component: Food Safety & Sanitation (2343)
 RDU: Environmental Health (207)

PCN	Job Class Title	Time Status	Retire Code	Barg Unit	Location	Salary Sched	Range & Steps	Budgeted Months	Split / Annual Count	Annual Salary	COLA	Premium Pay	Annual Benefits	Total Costs
18-#015	Environmental Health Tech.	FT	A	GP	Anchorage	2A	12B	12.0		31,308	0	0	15,944	47,252

Justification:

This position will be responsible for tracking compliance with the food worker certification requirement, deposit of the certification fees, issuance of the certifications and the distribution of training materials.

Funding Detail:

1156	Receipt Supported Services	100.00%	47,252
Total Funding:		100.00%	47,252

18-#016	Environmental Health Officer	FT	A	GP	Anchorage	2A	16B	12.0		41,136	0	0	18,257	59,393
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Justification:

This position will be responsible for providing food worker and Active Managerial Control (AMC) training, proctoring certification exams and "training the trainer" for 3rd party trainers in food worker and AMC requirements.

Funding Detail:

1156	Receipt Supported Services	100.00%	59,393
Total Funding:		100.00%	59,393

Component Summary:

Total New Positions: 2

Fund Description	Fund Percent	Fund Amount
1156 Receipt Supported Services	100.00%	106,645
Total Funding:	100.00%	106,645

Note: If a position is split, an asterisk (*) will appear in the Split/Count column. If the split position is also counted in the component, two asterisks (**) will appear in this column.