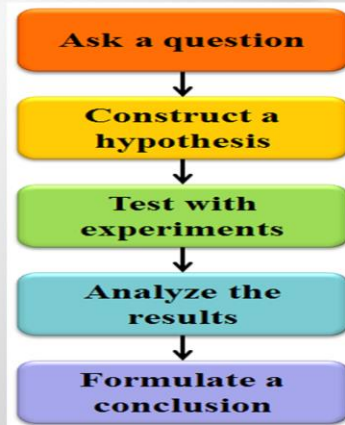


*Pilot Program:* Inspection reports vs. Internal Audits



## Steps

1. Question-Is there a better way to verify food safety at retail food establishments?
2. Hypothesis-Adequate oversight is possible with collaborative hazard analysis, off-site records review, and 3<sup>rd</sup>-party or in-house audits.
3. Developing Methods and Conducting the Experiment-Details to follow
4. Results-data analysis
5. Conclusions



We conducted this study by generally following the scientific method ☺

Our question was essentially whether we could develop a better way than on-site inspection to verify food safety at a retail food establishment. The hope was to utilize technology and records review in order to reduce the on-site inspection frequency. There was a considerable amount of effort spent designing the alternative food safety verification system. An even bigger challenge proved to be identifying what to measure to determine if this alternative system worked.

Once we figured these things out, we ran the experiment, gathered the data, analyzed it, and reached a conclusion.

## What is necessary for verification of food safety in a retail food establishment?

- An understanding of the level of risk in a retail food establishment  
→ Conduct a Hazard Analysis
- Knowledge of what must be done to reduce / eliminate risk →  
CCPs / Preventive Controls / CDC Risk Factors
- Procedures for gathering information and making an accurate  
assessment of whether CCPs / Preventive Controls are performed  
adequately.



We, and our collaborators at Kwik-Trip, felt that any alternative approach must be based on an understanding of risk, knowledge of controls, and effective monitoring and decision-making tools.

## Possible benefits from improving food safety verification at retail food establishments

A better system might:

- Provide more value for license fee \$
- Empower firm to verify food safety
- Involve less frequent on-site inspection
- Allow reallocation of resources for higher-risk businesses



A pilot project was conducted to determine if record review of Kwik Trip Stores over the course of two years would prove to be a satisfactory augmentation to onsite inspections. Chosen because they have a history of compliance and extensive processing records. The actual project, because of delays and personnel changes that affected planning, was spread over a roughly 5-year period.

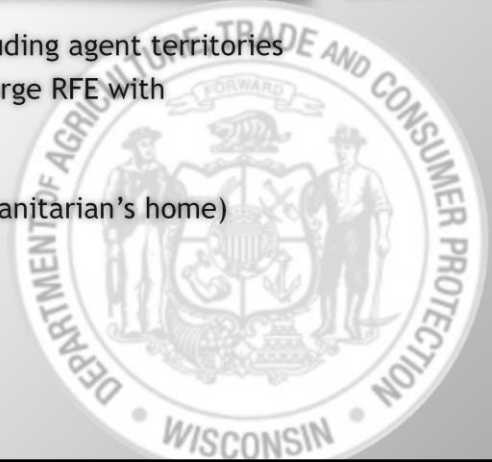
## Benefits of collaboration

- The state will receive more information and have a better understanding of food safety controls.
- Industry will build a stronger relationship with the state regulators.
- Partnership will allow for better resolution of food safety issues.



## Remembering 2009 – 2010 at WDATCP

- 8311 Retail Food Establishments (RFE)- including agent territories
- Goal was 1 inspection every 8 months for Large RFE with Potentially Hazardous Food
- Health Space was not in use
- No state-issued smart phones (land line at Sanitarian's home)



The work load was comparable to what it is today, but the standards and tools available have increased since this project was started.

## Remembering 2009 – 2010 at Kwik-Trip

- Ongoing food and environmental sampling program (indicators, *Listeria* spp.)
- Real-time transmission of delivery and storage temperature data, with automated alert system
- All WDATCP and agent inspection reports reviewed at main office, with needed corrections directives sent to store managers
- Store managers reported on corrective actions taken
- Trend analysis of debits and corrective actions done at central office
- Organized training program
- Internal and 3<sup>rd</sup>-Party auditing programs



Kwik-Trip had a fairly rigorous food safety system already in place.

## Let's do a pilot study!

- Must have mutually agreed-upon goals, steps, and evaluation methods
- On-site hazard analysis, visit to training program
- Initial issue: what is the risk level in a Kwik-Trip store? Difference of opinion
  - WDATCP opinion based on food characteristics → high
  - K-T opinion based on controls in place to reduce risk → low
- Agreement to focus on pre-cook and hot-hold systems
- Study will involve only stores under WDATCP jurisdiction
  - “Old”, “new”, and “acquisition” formats
- Potential Open Records issues

A lot of issues must be resolved before a collaborative pilot study can get off the ground. Agreement and resolution of issues requires trust, which was built through a variety of facility visits, sitting in on K-T training, and frank meetings.



## Initial Verification System

- Records review:
  - Training
  - Receiving
  - Cooking / hot-holding / cooling
  - Refrigerated / frozen storage
  - Microbiological sampling and analysis
- On-site verification (yearly)



This was our first attempt of what we would do instead of the standard “once every 8 months” on-site inspection. Note that the actual inspection frequency wasn’t slated to change all that much.

## Verification System, 2<sup>nd</sup> Try

- Quarterly
  - Review internal and 3<sup>rd</sup>-party audit reports
  - Review hot-hold temperature monitoring logs
  - Review hot-hold time monitoring logs
  - Review corrective action logs
  - Review deviation reports for temperature control and hot-holding time
- Semi-annually
  - Review debit trend analysis
  - Review microbiological sampling results
  - Review cold-temperature control deviation and corrective action logs
- After 18 months
  - WDATCP microbiological sampling

After a lot of thought, the plan was refined.

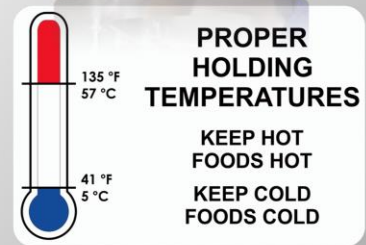
## Final Verification System

- 25 state-licensed Kwik Trip stores throughout Wisconsin.
- Kwik Trip share internal data through meetings, web access or electronically 3 times a year.
  - 3<sup>rd</sup>-party or internal audits, and trend analysis
  - Post-audit corrective action
  - Refrigeration/freezing deviations
  - Hot-holding logs
  - Illness log
- Shadow audit of KT Food Safety District Leader (FSDL) semi-annually.
- Review microbiological sampling results semi-annually

This is what we finally agreed on. Review HEAT records for refrigerators and freezers, temperature log books, illness logs, microbiological testing, menu changes, product discard logs, corrective action logs and third party or internal audits. Audit focused on reheating for hot hold, cold and hot hold, protection from contamination, food contact surfaces, good hygienic practices, bare hand contact, and hand wash facilities. Semi-annually shadow Food Safety District Leaders (FSDL).

## Focus on key debit items

- 5.2. Reheating for hot-holding
- 5.5. Cold and hot holding of PHF
- 5.7. Time
- 7. Protection from contamination
- 8. Food contact surfaces
- 11. Prevention of contamination with hands
- 12. Handwash facilities



Our hazard analysis identified these debit items as being worthy of focused attention during audits.

## What data do we use to make conclusions?

- Are internal monitoring and record-keeping systems adequate?
  - How do we “score” missing log entries?
- Do control stores have more debits than pilot study stores?
  - Create score sheet based on inspection cover sheet
  - Determine and compare inspection “scores”
- Are 3<sup>rd</sup>-party and internal audits reliable enough so that we can inspect less frequently?
  - Compare “Top 10 debit” lists → Problem of “cross walk” between inspection sheets
  - Would our inspectors see the same things as the 3<sup>rd</sup>-party and internal auditors?  
→ “Audit the auditor”
  - What if we evaluate some items that are not evaluated by 3<sup>rd</sup> party and firm, e.g. knowledge of operator ? Vice versa?

It's fine to operate a new system. But how do you figure out if it works better? We felt that generally we would need to have a control group of stores, under the standard inspection system, to use as a basis for comparison. We all know that it is not practical to use illness cases or outbreaks as a metric -tough to prove attribution, and events are infrequent.. One approach was to evaluate the completeness of the documentation and records review. This would only involve the pilot stores. Another approach was to compare debit numbers and severity in control and pilot stores. This approach might require the development of a score sheet, with numerical scores for each debit. Various debits can cover a range of risk levels – creating a subjectivity problem. We also focused on how to evaluate the reliability of the audit process. We would run into some problems related to differences in inspecting / audit technique and content.

## Comparison of WDATCP inspection results at control and pilot program stores

- 8 Control Stores inspected (6 old, 1 new, 1 acquisition)
  - 6 debits, 0 critical
  - In preceding inspection (13 - 36 months before): 9 debits, 2 were critical
- 8 Pilot program Stores inspected (5 old, 3 new)
  - 12 debits, 2 critical
  - In preceding inspection (30 - 50 months before): 14 debits, 5 critical
- What would you conclude?



Here is a description of the number and severity of debits noted by WDATCP inspectors at pilot program and control stores before and at the end of the study. What would you conclude? Number and severity of debits tended to drop with time. There tended to be more debits at pilot program stores, but that was the case before the study even started.

## Final decision on “Audit the auditor”

- Use a “standard” as the reference point for what an inspection or audit would debit, i.e. the standard represents the system
- WDATCP standard and Kwik-Trip standard watch the same internal or 3<sup>rd</sup>-party audit. The standards must not influence each other’s behavior.
- Do the standards agree on what they see?
  - Yes = the systems are equally stringent
  - No = one system (its inspectors / auditors) is less stringent



We decided this was the most feasible way to evaluate the 3<sup>rd</sup>-party and internal audit system. The observations of their “standard” was what we evaluated. If their standard would notice the same things our standard would notice, then the two systems could be considered equally stringent.

Kwik Trip Audit form	Inspection form
201 & 202	22
204	19, 16
109	5.6 A
110	16 5.6 B
115	5.4 A
116	7.4, 13B, 18 13C?
205	20
205	16 18
206	31 2, 18 6
208, 210	18 (2, 27, 18)
209	19
213	3
118, 119, 219, 222	23
217	26
218	27 31
224, 120, 214, 215	24
121	12A
122	9
123	11
124	8
125	10
229	12B, 28
230	25, 10A, 15
231	10 15
233	13B 26
127	16 13B
212	18 35 (37)
227	25
126	29 33
128	28
129	30 11?
130, 239, 240	39
225	35
226	36
236	35
237, 242	54
238	36
243	32, 19, 29

KT	WI
101	5.5A
103, 104	5.5B
111	4D 5.4C
108	4A, 4E
113	5.2 C, 5.1, 8, E, 5.2A
114	5.5 A, 5.7 A, 5.4 B
117	7E 7C
?	1
131	14
?	37
?	2A
?	27
Items not relevant?	

## Compare Forms- What to Use?

- Steritech Kwik Trip Audit Form
- DATCP Retail Food Establishment Inspection Report
- Wisconsin Standardization Inspection Report

Check to see if item numbers/codes match up. KT report marking form and standardization report marking form or standard state inspection form.



## “Audit the auditor” Trial Run

Mauston March 2013  
2 DATCP Food Scientists  
2 Kwik Trip Food Safety  
Officers  
1 Kwik Trip FSDL



Before starting the “audit the auditor” process, we went over Kwik Trip background such as; menus, processes & procedures to become more familiar with the overall operation of the stores. GRPs employee illness. Soups, F’real, datemarking, meat... FSDLs do their audits quarterly and they also have a third party audit done through Steritech bi-annually.

FSDL did their food safety audit while all 4 of us observed. After the process was complete we discussed forms, suggestions, and next steps. We firmed up schedules so that one FS and one KT QA shadows a FSDL at selected stores across the state. Note: industry considers good quality control as equivalent to food safety step.

## Overview of “Audit the auditor”

- Brief intro on site to store staff
- Let FSDL run through their audit process
- Shadow, address critical items missed before leaving area
- Once complete, print and review FSDL report
- How grade, trends, differences in doing audit
- Recommendations vs. misses
- Compile list at end

Explain purpose to store leader. Corporate had informed staff of project.

Grade – comparison of audit reports between FS & KT food safety. Look for trends whether similar or different. Date mark was a consistent difference. Flow of inspection between auditors was different.

Recommendations- dynamic inspection versus a check list approach.

Misses based upon food code and standardization process. Did FSDL ask employee process questions or assume procedures are being followed.

Mix it up so that David and I both get to go out with Marty and Dave but shadow the same FSDLs

## How we wrote up notes during “Audit the auditor”

- A practice that the auditor did or did not do
- A violation that the auditor did or did not observe and/or write
- Questions that came up to ask other standards for their interpretation
- Questions that came up to ask Kwik Trip
- Other notes

They have an audit check list to go through, but they should ask employees more food safety related questions.

Practice- have their own test strips or ask employee to use theirs, ask about thermometer calibration.

Violation-missed opportunity due to check list inspection process, recording cook temperature.

Interpretations-open package of cut greens from KT commissary or burritos removed from commissary package –what date required.

KT questions- how often is self serve fountain ice bin cleaned, is produce pre-washed or washed on site.

Other-Does Kwik Trip ever rotate FSDL areas? Familiarity can lead to assumptions.

STORE # DATE	Debit noted by KT	Debit not noted by KT
Debit noted by DATCP	Improper cold holding Sanitizer concentration-high/low Containers not labeled with common name Packaged products not labeled properly Equipment not clean/sanitized Single-service items not stored properly	Food contact surfaces not clean/sanitized Food/equipment not protected from contamination Food equipment not in good condition Physical facilities Chemicals
Debit not noted by DATCP	Date marking-breads, BBQ sauce, mustard Ice build up minimal in freezer Trash corral doors open but container lids closed Soup logs not completed per KT requirements	

Comparison table for inspection information. Compare KT & Steritech reports to DATCP audit reports and field inspection reports. Known disconnects were: date marking, cleaning

Known technical differences were: corporate policies.

Fixes to this are: train staff on dynamic inspection and standardization processes.

<u>Sanitarian</u>	<u>Store Location</u>	<u>Store Number</u>	<u>Store Type</u>	<u>Date of Inspection</u>	<u>KT (+) DATCP(+)</u>	<u>KT (-) DATCP (+)</u>	<u>KT (+) DATCP (-)</u>	<u>KT (-) DATCP (-) (46 total possible)</u>	
DSJ	Coon Valley	846	old	11/22/2013	2: 8, 36	2: 8, 5.6A	0	42	
DSJ	Fountain City	835	old	8-Nov-13	2: 16, 8		0	44	
DSJ	Mayville	488	old	11/11/2013	4: 5.5A, 13B, 12A, 39	1:30	0	41	
DSJ	Plymouth	470	new	11/7/2013	3: 16, 27, 16	4: 8, 25, 37, 21	0	39	
SD	Elkhorn	485	new	4/24/2013	3:35, 25, 16	2: 18, 5.5A	0	41	
SD	Mequon	325	old	4/24/2013	4: 15, 8, 5.5A, 13B		0	41	
SD	New London	791	acq.	5/9/2013	2: 10, 25	1:23	0	42	
SD	Waupaca	625	new	5/9/2013	5: 7C, 27, 23, 35, 37	1:23	0	40	
SD	Alma	802	old	11/22/2013	9: 5.5B, 5.6A, 25, 16, 18, 35, 27, 26, 24	6: 26, 7C, 18, 35, 36, 13B	0	31	
SD	Brillion	807	new	12/4/2013		1:36	2: 33, 27	0	43
SD	PdChien	842	old	12/5/2013	3: 5.5A, 8, 10	4: 26, 22, 23, 16	1:35	38	
SD	Tomah	484	old	12/11/2013	4: 5.5A, 13B, 16, 23		0	42	
DSJ	River Falls	301	old	5/9/2013	5: 5.2B, 7A, 13B, 9, 13	3:8, 13B, 36	1:23	37	
DSJ	Greenwood	315	old	5/9/2013	4: 16, 16, 13B, 23	2: 24, 28	0	40	

## “Audit the auditor” Data Analysis

- 14 Audits (6 by David, 8 by Sonja)
  - April - May, 2013 (4 Sonja, 2 David)
  - November - December (4 David, 4 Sonja)
- 9 old stores, 4 new stores, 1 “acquisition” store
  - Old stores: 5 David and 4 Sonja
  - New stores: 1 David and 3 Sonja
  - Acquisition: 1 Sonja
- 46 possible debits x 14 audits = 644
- Chi-squared analysis of 2 x 2 contingency table

## “Audit the auditor” results in 2 x 2 Contingency Table

	Kwik-Trip marked debits	Kwik-Trip did NOT mark debits
WDATCP marked debits	50	27
WDATCP did NOT mark debits	7	560

No statistically significant difference between WDATCP and Kwik-Trip standards ( $P < 0.05$ )  
But analysis is affected by large proportion of debits marked by either standard.

## Conclusions

- Inspection / auditing technique differences must be removed before we can be confident that oversight is equivalent
- Off-site records review has potential usefulness - if it follows a collaborative hazard analysis.
  - Technical Services section would have to expand if this approach were to be taken across industry
  - How would food safety systems in less progressive stores be evaluated? Competitive advantages? License fees?
- Industry was very open and willing to share information.
  - Shared goals
  - Trust
- Learned more of industry processes and controls.
- Industry had a better understanding of regulations.

