



The Road to ISO/IEC 17025 Accreditation: The Race to Improve Quality is On.

How Do We Fuel Up for the Future and Drive Towards Integration?

*Navigating speed bumps to implement and
attain an accredited processed food
sampling and testing program in Iowa.*

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**2015 APHL™
ANNUAL MEETING**

and ninth government environmental laboratory conference

May 18–21, 2015
Indianapolis
Indiana Convention Center



**Performance
Driven —
Racing to
Results**

Navigating speed bumps . . .

. . . Accredited ISO 17025 Processed Food Program

- 🍴 State Hygienic Laboratory
- 🍴 Developing Sample Plan Focus Area
- 🍴 Design Phase
- 🍴 Iowa's Sampling Plan
- 🍴 Challenges/Lessons Learned
- 🍴 PT provider challenges, and reporting via eLEXNET
- 🍴 Benefits: IDIA and SHL Perspectives
- 🍴 Acknowledgements
- 🍴 Contact Information





Iowa - State Hygienic Laboratory

- ❉ Iowa's Environmental and Public Health Laboratory
- ❉ Established in 1904 at the University of Iowa
- ❉ Three laboratory facilities in Iowa
- ❉ 24/7 courier service
- ❉ Food samples primarily related to outbreak or FERN surveillance or other projects
- ❉ ISO 17025 Year 3
- ❉ First year sampling plan
- ❉ USDA FERN Micro CAP
- ❉ FDA FERN Chem CAP



Sampling Plan Development

- ① Initial meeting between Iowa Department of Inspections and Appeals (IDIA) and State Hygienic Laboratory (SHL) to identify products and analytes
- ① Regular monthly conference calls to discuss logistics of upcoming sampling events
 - ① IDIA: chose sites, lead inspector, collection dates
 - ① SHL: chose analytes, methods, sampling containers, amount of sample needed, how to sample, questionnaires
 - ① Other logistics: type of samples, where and what time samples being dropped off.
 - ① SHL Ankeny Laboratory, north of Des Moines and daily courier to SHL Coralville Laboratory
 - ① If after hours drop off, arrangements were made





Sampling Plan Focus Areas

☉ Products with history of challenges

- ☉ apple cider: *Cryptosporidium* outbreak

- ☉ salsa/guacamole: *Salmonella* outbreak

☉ New Industries

- ☉ Aquaculture in Iowa!

☉ Products with broad distribution: Gelatin

- ☉ Environmental sampling pursuant to FDA contract (3 firms per year)

- ☉ Other products of interest to the state (ice and bottled water)



Iowa's Sampling Plan

Month	Product	#	Analytes
October, 2014	Apple Cider	4	Metals, pesticides and micro
November, 2014	Gelatin	4	Metals and micro
December, 2014	Aquaculture*	2	Metals, pesticides and micro
January, 2015	Bottled Water	3	SDWA regulated analytes
February, 2015	Gelatin	4	Metals and micro
March, 2015	Environmental	100	Micro only
April, 2015	Environmental	100	Micro only
May, 2015	Environmental	100	Micro only
June, 2015	Salsa	3	Metals, pesticides and micro
July, 2015	Aquaculture	2	Metals, pesticides and micro
August, 2015	Ice	3	SDWA regulated analytes



Challenges

- ① Sampling Plan
 - ① Identify analytes to determine
 - ① Set up bottle orders/containers
 - ① Receive samples
 - ① Determine appropriate methods
 - ① Complete and release analysis
 - ① Report to IDIA
- ① eLEXNET Reporting
- ① PT Samples for matrix/analytes
 - ① Pesticides
- ① SHL subject to numerous on-site evaluations



Behind the Scenes - IDIA

- ❶ Work with inspectors to identify potential facilities
 - ❶ Learn more about the product being produced.
 - ❶ Such as quantities and types of packaging
- ❷ Determine if the sampling will be conducted with an inspection or independent of an inspection
- ❸ Provide information on firm to SHL for production of sample transmittal documents.
- ❹ With very small facilities, schedule times.



Behind the Scenes - SHL

- 🔗 Set up result web access for inspectors
- 🔗 Build the bottle order
- 🔗 Obtain sampling codes from eLEXNET
 - 🔗 Lab product codes, reason collected, etc
- 🔗 Order standards, sampling devices and media
- 🔗 Send SHL collection form, sampling devices, and coolers to inspectors
- 🔗 Inform SHL staff what and when samples coming
- 🔗 Make arrangements for late sample deliveries



Order #: 69084



Pages in Order: 1 of 1

Containers in Order: 1

REPORT TO:

4274
STEVE MANDERNACH
IA DEPT OF INSPECTION & APPEAL
FOOD & CONSUMER SAFETY BUREAU
321 E 12TH ST 3RD FLOOR
DES MOINES, IA 50319

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Environmental
Sample Collection Form

State Hygienic Laboratory

Lakeside Laboratory
1638 Highway 86
Milford, IA 51351-7267
Phone # 712-337-3069

Ashley Laboratory
2220 S. Ashley Blvd.
Ashley, IA 50023-9093
Phone # 515-725-1600

U of I Research Park
2490 Crosspark Road
Coralville, IA 52241-4721
Phone # 319-335-4500 or
800-421-IOWA

<http://www.ahil.iowa.edu>

Requested Analyses/Tests

Total/Fecal coliform and E. coli MTF
E.coli O157:H7 BAX PCR
STEC BAX PCR
Salmonella PCR
Heavy metals
Insecticides

Complete or correct the following information

Collected Date: _____ <small>yyyy-mm-dd</small>	Collected Time: _____ <small>24 hour format hh:mm</small>
Client Reference: <u>wilsons orchard</u>	Collector: _____ <small>Print last, first name</small>
Location: _____ <small>kitchen sink, plant tap, etc.</small>	Location Street Address: <u>4823 DINGLEBERRY ROAD</u>
Location City: <u>IOWA CITY</u>	Location State: <u>IA</u>
Location Zip Code: <u>52240</u>	Collector Phone: _____ <small>000/111-2222</small>
Description: <u>pasteurized apple cider</u>	Project Name: _____ <small>Laboratory approved projects only</small>
Lab Product Code: _____	Country Code: <u>US</u>
Reason Collected: <u>STATE-FDA SURVEILLANCE</u>	

Chain of Custody/Tracking Signatures

Relinquished By: _____	Date/Time: _____ <small>year / mm / dd Military Time</small>
SHL Sample Receiving Custodian: _____	Date/Time: _____ <small>year / mm / dd Military Time</small>
Relinquished By: _____	Date/Time: _____ <small>year / mm / dd Military Time</small>
SHL Sample Receiving Custodian: _____	Date/Time: _____ <small>year / mm / dd Military Time</small>

For SHL Use Only – Please do not write below this line

Received By: _____ pH: _____

Evidence of Tampering: Yes No Evidence of Cooling: Yes No

Date Printed: 2014-10-15

Bottles Received: _____ Temperature (Celsius): _____

BUILD ID _____

BUILD ID _____

PLACE THE ACCESSION LABEL WITHIN THIS BOX





Apple Cider Pesticides

- What pesticides to test for?
 - Contacted ISU Extension for what *can* be applied
 - Requested growers to indicate what *was* applied
- What method to use?
 - AOAC2007.01– QuEChERS extraction followed by dispersive solid-phase extraction cleanup. Analysis by LC/MS/MS and GC/MS/MS
- Results: all pesticides were below quantitation limits

Apple Cider Pesticides



2014 Midwest Tree Fruit Spray Guide





Apple Cider

🍏 Tests:

🍏 Pesticides:

🍏 Azoxystrobin,
Chlorpyrifos, Imidacloprid, Tebuconazole, Captan,
Phosmet, Esfenvalerate

🍏 Metals

🍏 Parasites: *Cryptosporidium* and *Giardia*

🍏 The use of indicators:

fecal coliform and *E.coli* and if high,
bacterial enteric pathogens (*E.coli*
O157:H7; *Salmonella*)





Apple Cider Microbiology Results

🍏 Pasteurized Apple Cider

- 🍏 Total and Fecal coliform & *E.coli* MPN: <0.18 /gram

🍏 UV treated Apple Cider

- 🍏 Total coliform MPN: **160** /gram
- 🍏 Fecal coliform MPN: **7.9** / gram
- 🍏 *E.coli* MPN: **7.9** / gram
- 🍏 *Cryptosporidium* and *Giardia*: negative (<2/L)
- 🍏 *Salmonella*, *E.coli* O157:H7 and STEC (BAX PCR): negative



UV Treated *Apple Cider*

- 🍏 UV-treated cider can be sold in Iowa
- 🍏 Coliform monitoring indicates sanitary problem
- 🍏 Processes evaluated (Carl Huffman, FDA State Liaison); gaps in documentation
 - 🍏 UV light had been sent in for calibration
 - 🍏 Possible post process contamination
- 🍏 Repeat samples collected (both raw and UV treated) to demonstrate 5 log removal
- 🍏 Raw cider bacterial results were very low and UV treated sample results were all negative



Gelatin Lessons Learned

- Tests (EU requirements)
 - Aerobic Plate Count
 - *Staphylococcus aureus* Plate Count
 - *Salmonella* PCR
 - Heavy Metals
- Types of Gelatin
 - Animal types: Pork/beef
 - two grades: hi and low

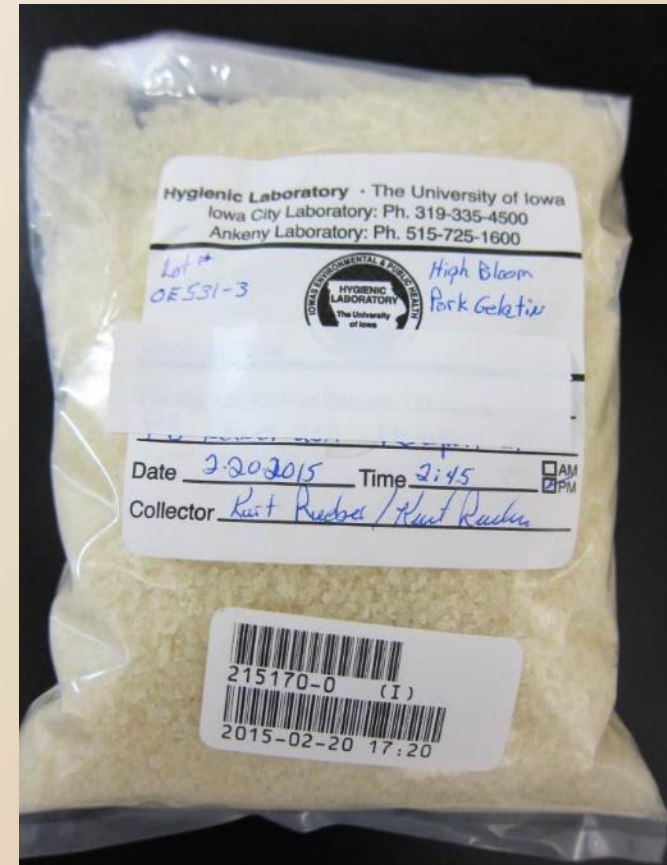


Photo by Nancy Hall, SHL



Gelatin Microbiology Problems

- Papain Contaminated with *Salmonella* C1
- Papain is a proteinase reagent used for the testing of gelatin; crude papaya latex
- Replacement lot also contaminated
- Difficulties finding uncontaminated product
- Contacted the FDA Denver Laboratory and Tom Hammack, CFSAN
- Alternative product found: Acros Organics
- Also, coliform assay worked better with 1:10 dilution in single-strength than 1:1 product/double-strength media











Aquaculture

- 🐟 Planned to test the water, fish and microgreens
- 🐟 Unfortunately, facility closed for winter holiday season
- 🐟 Fish will not be ready for sampling until mid/late April 2015





Aquaculture Questionnaire

-  Purpose of questionnaires: better understanding of processes to aid in inspection, sampling and result interpretation
 -  What type of fish do you use in your growing tanks?
 -  What is the typical size of the fish once it is harvested and processed?
 -  Once processed, is the fish stored frozen or refrigerated?
 -  If upon the date of our visit you do not have any fish processed, would you be willing to process a couple of fish for our observation?
 -  What type of greens are you growing at this time and is it likely that there would be harvested greens at the time of our planned visit?
 -  What is your source for operational water (private well or municipal water such as rural water)?
 -  Are the growing beds in the greenhouse all connected to the same water distribution system from the fish grow tanks, or are there multiple systems? If multiple, how many?



eLEXNET

- 🖥️ Last two years was able to perform spreadsheet upload for the couple hundred environmental samples
 - 🖥️ First year: worked with eLEXNET staff to develop spreadsheet
 - 🖥️ Second year: the spreadsheet template changed so had to rearrange columns for upload
- 🖥️ Currently working on developing the spreadsheet for the multi-analyte chemical analytes (with microbial tests)
 - 🖥️ Chemists are preparing analyte crosswalk for IT SQL
- 🖥️ Bacteria indicator tests added



Pesticides PT Samples

Sample 773 will be provided as a fruit or vegetable matrix which will **contain detectable levels of up to 10 pesticides** selected from the list given in **Appendix B.**

Sample 777 will be provided as a dried tea matrix which will contain detectable levels of up to 10 pesticides selected from the list given in Appendix C.

Participants will be required to screen the sample provided and report the presence of any pesticides found above their routine reporting limits. Each pesticide detected in the sample should also be quantified.



Pesticide PT Sample

APPENDIX B - Potential pesticides residues (parent compounds only unless stated) Sample 773 - Fruit/vegetable matrix

2,4-D	Chlorfenapyr	Diphenylamine	Heptenophos
2-phenylphenol	Chlorfenvinphos	Diuron	Hexachlorobenzene
Abamectin	Chloridazon	Endosulfan ³	Hexaconazole
Acephate	Chlorobenzilate	Epoxiconazole	Hexazinone
Acetamiprid	Chlorotoluron	Ethiofencarb ¹	Hexythiazox
Acetochlor	Chlorpropham	Ethion	Imazalil
Acrinathrin	Chlorpyrifos	Ethofumesate	Imidacloprid
Acrinathrin	Chlorpyrifos-methyl	Ethoprophos	Indoxacarb
Alachlor	Chlorthal-dimethyl	Etrinfos	Ioxynil
Aldicarb ¹	Chlorthiophos	Fenamidone	Iprodione
Aldrin	Chlortoluron	Fenamiphos	Iprovalicarb
Aminocarb	Clofentezine	Fenarimol	Isocarbofos
Amitraz	Clomazone	Fenazaquin	Isodrin
Asulam	Clothianidin	Fenbuconazole	Isofenphos
Azinphos-ethyl	Cyanazine	Fenhexamid	Isofenphos-methyl
Azinphos-methyl	Cyanophenphos	Fenitrothion	Isoproturon
Azoxystrobin	Cycloxydim	Fenoxycarb	Isoxaben
Benalaxyl	Cyfluthrin	Fenpropathrin	Kresoxim-methyl
Benfuracarb	Cymoxanil	Fenpropimorph	Lambda-cyhalothrin
Benthiavalicarb	Cypermethrin	Fenpyroximate	Lenacil
Benthiavalicarb-isopropyl	Cyproconazole	Fenthion ¹	Lindane
Bifenthrin	Cyprodinil	Fenvalerate	Linuron
Biphenyl	Cyromazine	Fipronil ²	Malathion
Bitertanol	DDT ⁴	Fluazinam	Mecarbam
Boscalid	Deltamethrin	Flubendiamide	Mepanipyrim
Bromophos-ethyl	Diazinon	Flucythrinate	Metaconazole
Bromophos-methyl	Dichlobenil	Fludioxonil	Metalaxyl
Bromopropylate	Dichlobutrazole	Flufenoxuron	Metamitron
Bromoxynil	Dichlofenthion	Fluopicolide	Metazachlor
Bromuconazole	Dichlofluanid	Fluoxastrobin	Methabenzthiazuron
Bupirimate	Dichlorvos	Flurochloridone	Methacrifos
Buprofezin	Dicloran	Fluroxypyr	Methamidophos
Cadusafos	Dicofol	Flusilazole	Methidathion
Captan	Dieldrin	Flutriafol	Methiocarb ¹
Carbaryl	Difenoconazole	Fluvalinate-tau	Methomyl
Carbendazim	Diflubenzuron	Folpet	Methoxyfenozide
Carbofuran	Diflufenican	Fonofos	Metolachlor
Carbophenothion	Dimethoate	Fosthiazate	Metolcarb
Chlordane (cis)	Dimethomorph	Furalaxyl	Metoxuron
Chlordane (trans)	Dimoxystrobin	Furathiocarb	Metribuzin
	Dinotefuran	Heptachlor	Mevinphos



Pesticide PT Sample

Monocrotophos
Monolinuron
Monuron
Myclobutanil
Nitenpyram
Nitrofen
Nuarimol
Omethoate
Oxadixyl
Oxamyl
Oxychlorane
Oxydemeton-methyl
Oxyfluorfen
Paclobutrazol
Parathion
Parathion-methyl
Penconazole
Pendimethalin
Permethrin
Phenothrin
Phenthoate
Phosalone
Phosmet
Phosphamidon
Picoxystrobin
Pirimicarb
Pirimiphos-ethyl
Pirimiphos-methyl
Prochloraz
Procymidone
Profenofos
Promecarb
Prometrym
Propamocarb
Propaquizafop
Propargite
Propazine
Propetamphos
Propiconazole
Propoxur
Propyzamide

Proquinazid
Pymetrozine
Pyraclostrobin
Pyrazophos
Pyrethrins
Pyridaben
Pyridaphenthion
Pyrifenoxy
Pyrimethanil
Pyriproxifen
Quinalphos
Quinoxifen
Quintozene
Spirodiclofen
Spiromesifen
Tebuconazole
Tebufenozide
Tebufenpyrad
Tebuthiuron
Tecnazene
Teflubenzuron
Tefluthrin
Terbacil
Terbutylazine
Terbutryn
Tetrachlorvinphos
Tetraconazole
Tetradifon
Tetramethrin
Thiabendazole
Thiacloprid
Thiamethoxam
Thiodicarb
Tolclofos-methyl
Tolfenpyrad
Tolyfluanid
Triadimefon
Triazophos
Triclopyr
Trietazine
Trifloxystrobin

Triflumizole
Trifluralin
Trifluralin
Tritconazole
Vinclozolin
Zoxamide

Note: Metabolites of the substances listed may also be included

¹ Sum of parent plus sulfoxide and sulfone

² Parent plus sum of sulfone

³ Sum of alpha, beta and sulfate

⁴ Sum of pp'-DDT, op'-DDT, pp'-DDE and pp'-TDE



Benefits: IDIA Perspective

- Inspectors gain more experience at sample collection; including chain of custody procedures, filling out forms, aseptic technique, various collection devices and vessels
- Discovered problem areas (e.g. treated cider)
- Improved communications and build relationships with SHL
- Improved our environmental sampling program; used in outbreak situation Dec 2014 and found the implicated pathogen in the environment



Benefits: Lab Perspective

- Gain more experience with difficult matrices (e.g. gelatin, apple cider)
- Gain more experience with testing food samples in general
 - Every food is different and many times difficult, especially for chemical area
- Improve our environmental sample program in general; having all the sampling devices on hand; bottle orders built and ready to go at moments notice (e.g. Fri afternoon!)
- Build capacity, capability and outbreak preparedness (especially processing 100 samples in one day)
- Build better communication and improve relationships with IDIA



SHL Accreditations/Certifications

- Multiple on-site evaluations this year
- American Industrial Hygiene Association (AIHA-LAP)
 - **Ankeny – April 21-24, 2015**
 - Industrial Hygiene (IHLAP)
 - Environmental Lead (ELLAP)
 - FoodLAP
 - Coralville – TBD IHLAP expires 12/01/15 adding FoodLAP
- Clinical Laboratory Improvement Amendments (CLIA) – Chemical Threat and Blood Lead
 - Ankeny – June 1-5, 2015
 - Coralville – June 1-5, 2015
- National Environmental Laboratory Accreditation Program (NELAP – Oregon)
 - Ankeny – week of August 31-September 4, 2015
 - Coralville – week of October 12-16, 2015
 - Milford (Lakeside Lab) – week of August 31-September 4, 2015

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- Various Iowa facilities chosen this year
- Julie Vosilus, FDA State Liaison
- Tom Hammack, CSFAN
- eLEXNET help desk staff
- Eyal Rand, GlobalNet Services



Thank you! & Contact Information

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