

The Value of Third Party Independent Audits in Assuring Food Safety: Are They Truly Independent?

A Presentation at IAFP's Symposium on *Salmonella* in Peanut Products –
Understanding the Risk and Controlling the Process

Dr. Paul A. Hall

President

AIV Microbiology & Food Safety Consultants, LLC

Hawthorn Woods, IL USA

March 26, 2009
Arlington, Virginia



Producing Safe Food is Our Top Priority!

- Consumer protection and trust
 - Consumers must be able to trust the brands they buy and the food they eat
 - Food safety is absolutely critical to that trust
- Business survival/self-interest
 - Our brands are our most important asset
 - History is replete with brands and businesses being destroyed because of a lapse in food safety
- Industry responsibility
 - Moral obligation to produce food as safe as practical
 - Industry pledge not to make safety a competitive issue



Food Manufacturing Statistics

- There are almost 31,000 food and beverage manufacturing plants in the U.S. owned by about 28,500 companies (2002 Census of Manufacturers data)
- These plants employed about 1.6 million workers in 2005 (about 12% of all U.S. manufacturing employment and just over 1% of all U.S. employment) according to USDA's Economic Research Service
- These plants account for about 13% of the value of shipments from all U.S. manufacturing plants
- Small plants (1-19 employees) account for about 69% of all plants, but only 4% of the total value of shipments.
- Large plants (100 or more employees) account for about 77% of shipment value, but only 12% of plants.



*Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always*



Our Global Food Supply

- Food is a heavily traded commodity
 - Global agricultural trade in 2005 was valued at \$852 billion (WTO, 2006)
- Food imports into the U.S. is averaging >10% annual growth
 - Projected to climb to over \$80B in 2009
 - >9M entries of imported food into the U.S. passing through >300 entry points each year

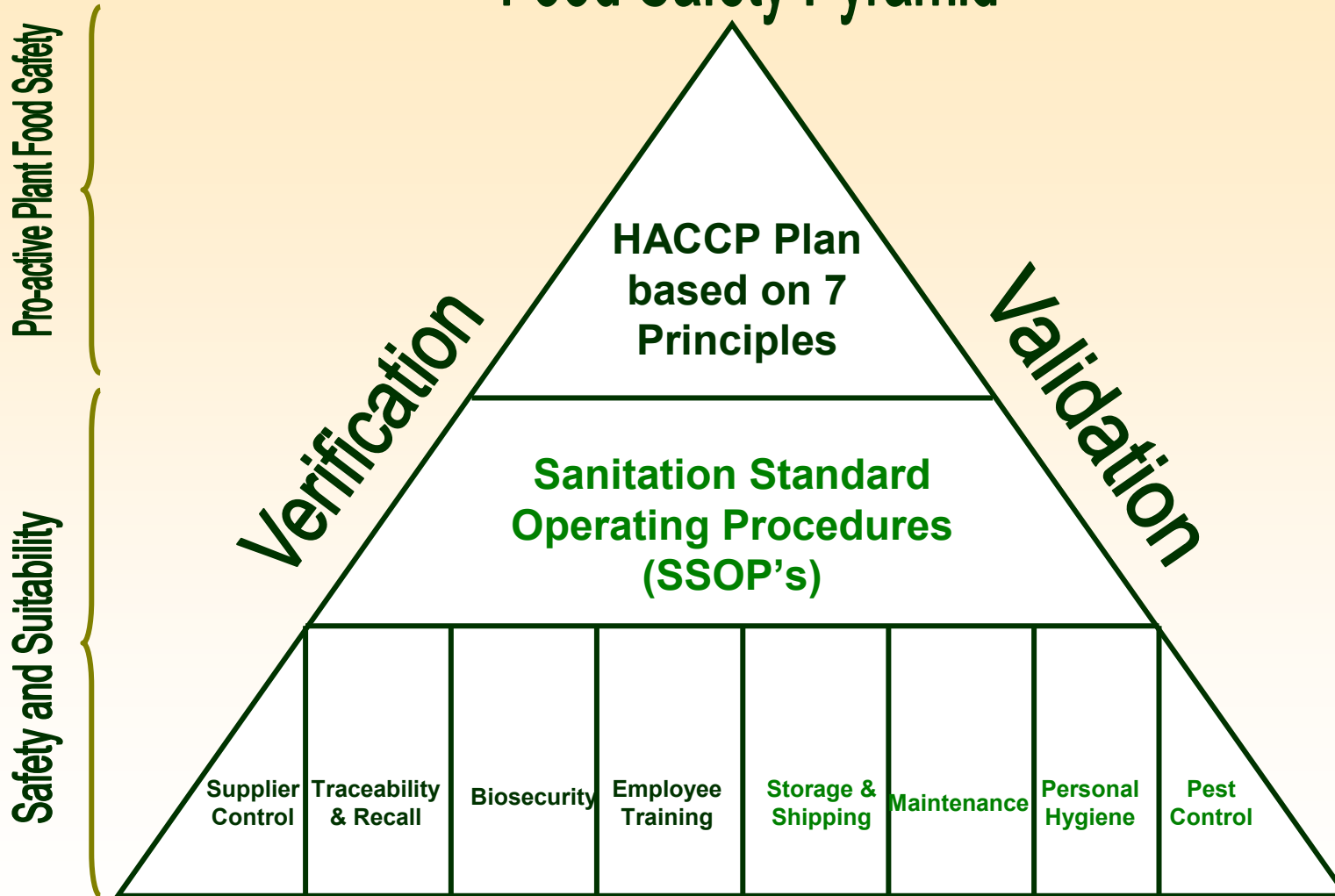


*Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always*



Elements of a Strong Food Safety System

Food Safety Pyramid



Programs in light green font are viewed by USDA as the Sanitation Program (9 CFR 416)

Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always

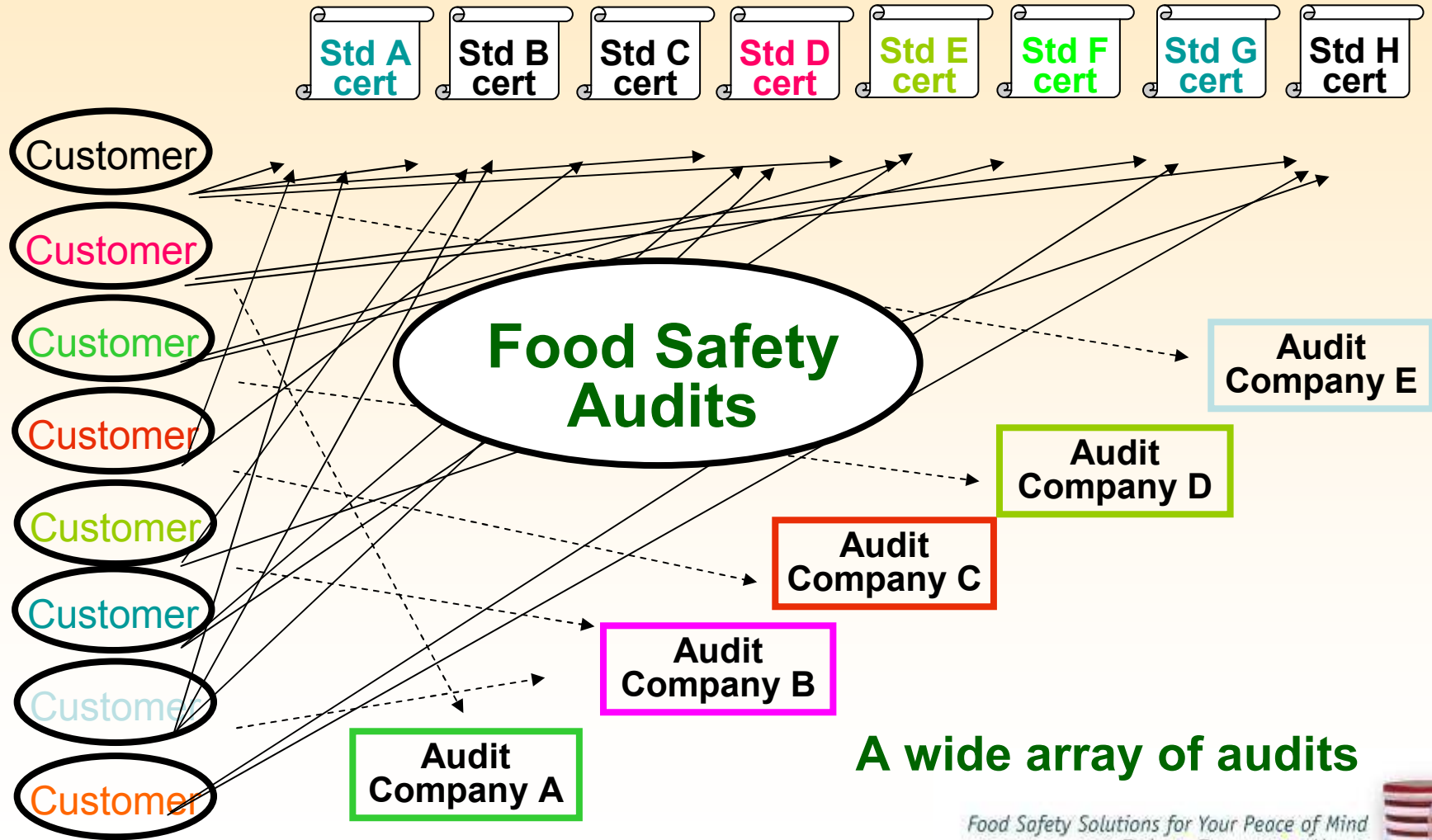


Ensuring Food Safety Through Certification

- The food and beverage industry has become increasingly reliant on independent third party audits and certification to assure that their processes, personnel, and establishments conform to pre-determined food safety and other standards.
- Certification Bodies conduct audits and certify compliance to the designated standards.
- Accreditation Bodies accredit certification bodies and are typically licensed by the Standard Owner (e.g. ISO Guide 65)
- Accredited Certification Bodies are 3rd party auditing firms that must meet specific requirements for procedures and practices



Current Audits & Standards



A wide array of audits

*Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always*



U.S. Food and Drug Administration Guidance for Industry Third-Party Certification Programs

- In January, 2009 the FDA issued a guidance document for industry voluntary third-party certification programs for foods and feeds
- The federal government supports voluntary certification programs as one way to help ensure products meet U.S. safety and security standards and to allow federal agencies to target their resources more effectively.
- FDA's Food Protection Plan released on November 6, 2007 emphasizes certification as a way to help verify the safety of products from a growing food establishment inventory, both domestic and foreign



*Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always*



U.S. Food and Drug Administration Guidance for Industry Third-Party Certification Programs

- The recommended certification process outlined in the FDA guidance document provides provisions for:
 - An official application process
 - The certification process including an establishment audit
 - Provisions and conditions for recertification based on risk (minimum frequency is once every 2 years)
 - Provisions for withdrawing certification (including immediate notification of FDA)



Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always



U.S. Food and Drug Administration Guidance for Industry Third-Party Certification Programs

- To facilitate an FDA assessment, the certification body should seek accreditation from an accreditation body that is operating in accordance with the ISO/IEC standard 17011:2004, *Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*
- The following attributes should be included as part of the third party certification program:
 - Authority of the Certification Body
 - ✓ Authority to perform audit activities
 - ✓ Authority to examine and gather records and other information
 - ✓ Authority to collect and analyze samples
 - ✓ Authority to assess and report on compliance with certification criteria



U.S. Food and Drug Administration Guidance for Industry Third-Party Certification Programs

➤ Qualification and Training for Auditors

- ✓ Recommends that all auditors meet or exceed the minimum educational requirements applicable to FDA Consumer Safety Officers (CSO's)
- ✓ The certification body should also have a training plan that ensures that all auditors receive the necessary training to adequately perform their work assignments (should provide both basic and advanced audit training)



U.S. Food and Drug Administration Guidance for Industry Third-Party Certification Programs

➤ Elements of an Effective Audit Program

- ✓ Risk-based
- ✓ Written policies and procedures
- ✓ Verification that the establishment meets certification criteria
- ✓ Process for addressing establishment complaints about audits
- ✓ Documentation and recordkeeping



U.S. Food and Drug Administration Guidance for Industry Third-Party Certification Programs

- Quality Assurance Program for Audits and Auditors
 - ✓ Field evaluation of audits to verify audits are consistent
 - ✓ Audit report evaluation
 - ✓ Sample report evaluation
 - ✓ Individual auditor performance
- Compliance and Corrective Action
 - ✓ The certification body should use a risk-based approach to determine when an investigation, follow-up, or re-audit is necessary
 - ✓ Evaluate whether the establishment has executed corrective actions
 - ✓ Withdraw certification if the establishment fails to take corrective actions



U.S. Food and Drug Administration Guidance for Industry Third-Party Certification Programs

➤ Industry Relations

- ✓ The certification body should provide establishments seeking certification with information about current FDA requirements and guidance
- ✓ It is preferable that the certification body be actively involved in regulatory, scientific, industry, and other external activities

➤ Resources

- ✓ The third party certification body should have sufficient resources to accomplish the elements of the certification program

➤ Self-Assessment of the Overall Certification Program

- ✓ Assesses performance and identifies strengths and weaknesses



U.S. Food and Drug Administration Guidance for Industry Third-Party Certification Programs

➤ Laboratories

- ✓ The certification body should have access to appropriate laboratory services needed to support the audit

➤ Notification to FDA

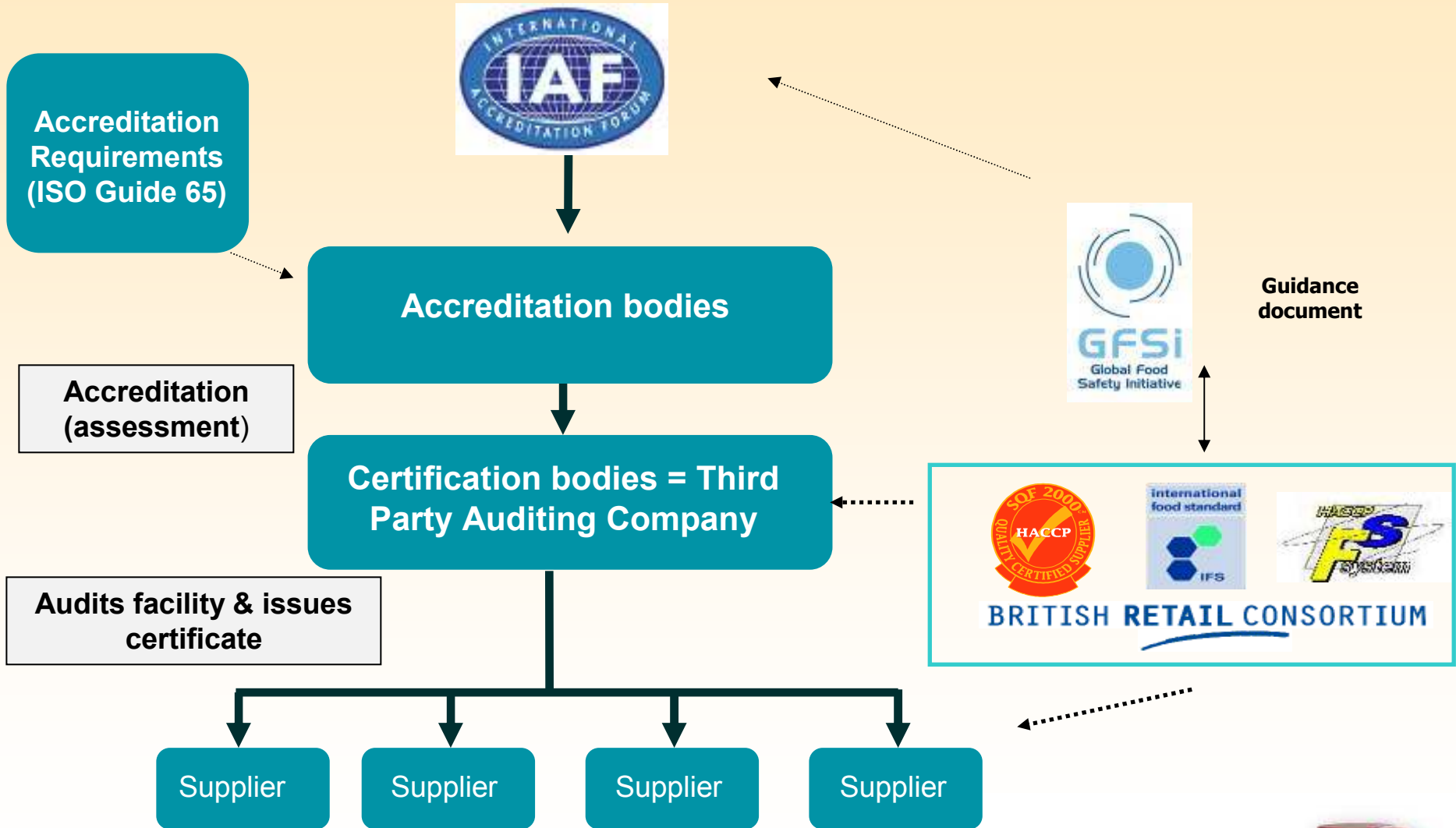
- ✓ Product safety issues
- ✓ Withdrawing certification
- ✓ Changes to the certification program

➤ Conflict of Interest

- ✓ The certification body and its auditors should be free of any conflicts of interest that threaten impartiality



Food Safety Certification Framework



Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always



Advantages of Using Accredited Certification Bodies

- Impartial – no conflict of interest – maybe!
- Qualified, trained auditors – maybe!
- Licensed by the Standard owner and accredited to the Standard
- Assess to the Standard, wherever the audit occurs
- Certification Body, not the auditor, determines the certification status of the establishment
- Each auditor is required to maintain category-specific competencies



Recent Food Safety Issues with Certified Facilities

- Peanut Corporation of America – *Salmonella*
- Keystone Food Products of Easton, PA (Veggie Booty) – *Salmonella*
- Westland/Hallmark Meat Company (Ground Beef) – Use of downer cows
- Nebraska Beef (Ground Beef) – *E. coli* O157:H7
- Multiple Suppliers (Spinach) – *E. coli* O157:H7
- Animal Feed (Germany) – Dioxin contamination



Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always



Third Party Certification Comes Under Fire

- **New York Times (03/06/09) – *Food Problems Elude Private Inspectors***

“The contributions of third-party audits is the same contribution of mail-order diploma mills”

“The only thing that matters is productivity... you only get in trouble is someone in the media traces it back to you, and that’s rare, like a meteor strike”

“Another audit of the peanut plant... Raises further questions about the usefulness of private audits. That audit found nearly two dozen problems that it characterized as “minor”, but it nevertheless gave the peanut plant an overall score of 91 out of 100”

- **The Atlanta Journal Constitution (03/08/09) – *Peanut Inspection System Filled With Holes***

“It is almost impossible to reconcile inspection reports with findings after outbreaks... You look at them and think, ‘Gee, were they in the same facility?’”



Third Party Certification Comes Under Fire

- **U.S. News & World Report (09/10/08) – *Food Safety’s Dirty Little Secret***

“Increasingly the government is leaving the job in private hands”

“These audits are like icing on the cake of litigation... Every major manufacturer does them, and every major manufacturer pays no attention to them”

“Private auditors must be part of the answer... The challenge is to make sure they’re qualified”

- **Chicago Tribune (03/20/09) – *Industry Inspectors Failed to Find Festering Problems at Peanut Corp., Lawmakers say***

“Lawmakers said the food industry’s private inspection system failed to catch filthy conditions because the company itself hired the inspectors”

“There is an obvious and inherent conflict of interest when an auditor works for the same supplier it is evaluating”



Empirical Data on the Reliability of Third-Party Audits

Auditing Results of Certification Bodies (Lower Saxony; Pork)

Certification Body	QS Status 1 (100-90%)	QS Status 2 (<90-80%)	QS Status 3 (<80-70%)	Certification Refused (<70%)
A	98.6	1.4	0.0	0.0
B	98.3	1.2	0.1	0.3
C	95.3	3.9	0.2	0.6
D	93.7	3.6	0.0	2.8
E	92.9	2.9	0.0	4.3
F	92.7	5.4	0.2	1.7
G	90.4	7.4	1.1	1.2
H	86.3	1.4	0.0	12.3
Average	93.5	5.0	0.5	1.0

Source: Albersmeier, F., et al. The reliability of third-party certification in the food chain. From checklists to risk-oriented auditing. Food Control (2009), doi:10.1016/j.foodcont.2009.01.010

Empirical Data on the Reliability of Third-Party Audits

Comparison of Auditing Results by Individual Auditor (Lower Saxony; Pork)

Auditor	QS Status 1 (100-90%)	QS Status 2 (<90-80%)	QS Status 3 (<80-70%)	Certification Refused (<70%)	Duration (hh:mm)
A1	98.3	1.7	0.0	0.0	01:32
B1	100.0	0.0	0.0	0.0	01:27
C1	98.1	1.3	0.2	0.4	01:24
D1	93.2	3.8	0.0	3.0	01:35
E1	91.1	3.6	0.0	5.4	01:44
F1	96.0	2.0	0.0	2.0	01:27
G1	74.9	18.2	3.7	3.2	01:29
H1	86.3	1.4	0.0	12.3	01:56
Average	93.5	5.0	0.5	1.0	01:38

Source: Albersmeier, F., et al. The reliability of third-party certification in the food chain. From checklists to risk-oriented auditing. Food Control (2009), doi:10.1016/j.foodcont.2009.01.010



Empirical Data on the Reliability of Third-Party Audits

Conclusions from Study

- There are highly significant differences between the auditing judgments of certification bodies who have audited pork producers in Lower Saxony
- It seems highly likely that the reported variations may result from weaknesses in the auditing process
- These differences, which can also be demonstrated in other states and sectors, point to nonconformance in auditing practices



Empirical Data on the Reliability of Third-Party Audits

Conclusions from Study

- It cannot be ruled out that know-how differences between the individual auditors and varying auditing intensities might be responsible for the variations
- Economic dependencies could be a second potential cause of varying audit results
 - ✓ “The pronounced stress of competition and the low prices that certifiers report...can lead some auditors to deliberately audit inattentively in order to minimise their costs and at the same time increase their chance of recontracting and being recommended”



Auditor Calibration Procedures

- Certification Bodies use defined auditor calibration systems
 - Required auditor professional development
 - Desk assessments of auditor work including planning and organizational skills
 - Shadow audits by lead auditor assessing pre-, actual, and post-audit work
 - Review of reports
 - Maintain a category-specific competency matrix per auditor
- Accreditation Body reviews Certification Body's auditor calibration processes
- Accreditation Body conducts shadow audits of Certification Body's auditors



Auditor Controls



- Follows Certification Body's SOP's
 - Represents the Certification Body and the Standard Owner
- Audits only to approved food sectors
- Practices impartiality and confidentiality
 - Certification Body requirements eliminate conflict of interest
 - Independent of the auditee and/or customer
 - Accreditation rules restrict consulting with the auditee
- Verifies and reports factual compliance and details non-compliance issues
 - Assessment process challenges the facility to demonstrate compliant control systems and procedures
- Auditors do not make the certification decisions
- Auditor rotation requirements helps maintain audit integrity



With These Checks and Balances In Place – Why Is There A Stream of Illness Outbreaks?

- ***Differences in experience levels of individual auditors***
 - ✓ Even though auditors may be sector specific, their experience level in that sector can differ
 - ✓ This leads to difficulties in asking the right follow-up questions
- ***Auditors are not “Jacks-of-all-trades”***
 - ✓ Most are not process, mechanical, electrical, design, packaging, or system engineers
 - ✓ May not be experts in product formulation, sanitary design, sanitary practices, or other relevant disciplines
 - ✓ Quality background vs. food safety background
- ***Time and cost***
 - ✓ Many audits are done in one day or less – this is not enough time to do a comprehensive food safety assessment
 - ✓ Some companies look for the cheapest alternative



With These Checks and Balances In Place – Why Is There A Stream of Illness Outbreaks?

- ***Deceit on the part of the facility being audited***
 - ✓ It is difficult for auditors to address withheld information or data that is pertinent to the audit or to pick up on fabricated/falsified data
- ***Checklists vs. dynamic, risk-based audits***
 - ✓ Virtually all auditors use some form of checklist
 - ✓ However, without keen insight, knowledge, and the ability to ask the right questions, checklists are superficial – they're simply checklists
- ***Too much “paper” review and not enough time spent on the plant floor***
 - ✓ Auditors need to strike a balance between documentation review (which is important) versus time spent in the plant (which is crucial)
- ***Lack of follow-up***
 - ✓ Often, there is little follow-up by auditors to ensure that deficiencies have been addressed in a timely manner



With These Checks and Balances In Place – Why Is There A Stream of Illness Outbreaks?

- ***Lack of audit depth***
 - ✓ Virtually all audits do not encompass physical audits of suppliers providing ingredients and materials to the facility being audited
 - ✓ Virtually all audits do not encompass physical audits of outside testing laboratories that the facility being audited may be using for microbiological and other testing
- ***Over-reliance on audits by companies***
 - ✓ Some companies believe that if they “pass” an audit, then everything must be o.k. – they become complacent... until the next audit
- ***Announced vs. unannounced audits***
 - ✓ Most third party audits are announced, giving the facility time to prepare for the audit
 - ✓ Some Certification Bodies and/or auditors provide advice to the facility on how to prepare for the upcoming audit



With These Checks and Balances In Place – Why Is There A Stream of Illness Outbreaks?

- ***Implicit versus explicit conflict of interest***
 - ✓ Both Accreditation and Certification Bodies go to great lengths to assure impartiality and prevent explicit conflict of interest issues with auditors
 - ✓ However, they are “for-profit” entities, therefore, issues with implicit conflict of interest issues may persist, since, typically, the facility or the company pays for the audit
 - ✓ Consequently, some auditors may tend not to be as tough in their evaluation as they otherwise might be
- ***Companies do little or nothing with the audit results***
 - ✓ Some companies do not react with a sense of urgency to audit results – particularly on those items that are described as minor deficiencies
 - ✓ Some companies even address major deficiencies such as roof leaks with only temporary or stop-gap measures and do not devote the proper investment/resources to the correct long-term solution



Given the Deficiencies in Third Party Audits – Are They of Any Value?

- Some skeptics believe that third party audits are not truly independent and, by nature, are suspect and of minimal or no value
- On the other end of the spectrum, some proponents of third party audits believe they are an essential component to consumer protection
- The truth lays somewhere in the middle... third party audits provide some degree of value, but they definitely are not infallible
- At the end of the day, the value a company gets out of their third party audits is directly proportional to their commitment to aggressively following through on audit findings, including minor deficiencies
- Accreditation and Certification Bodies need to acknowledge that the approach to third party certification and audits needs strengthening



A Word on Government Inspections

- Both federal and state government regulators have to share some culpability in these outbreaks
- Almost all facilities that were involved in outbreaks have been audited by both federal and state inspectors
- It is well-documented that many deficiencies found in these establishments should have been cited by government inspectors or timely follow-up should have been conducted to ensure identified deficiencies were corrected
- Government regulatory bodies at both the state and federal levels need sufficient resources to upgrade their inspection staffs



*Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always*



Thoughts on Future Direction

- Accreditation and Certification Bodies should move away from inspections by single auditors
 - ✓ Experience shows that a multi-disciplinary food safety and quality assessment provides a much more thorough audit than can ever be done with only one individual
 - ✓ Disciplines should be tailored to the food sector being audited, and should include individuals with backgrounds in sanitation and sanitary design, microbiology and food safety, engineering, product formulation, quality assurance, among other disciplines
- Sufficient time should be given for the auditing time to do their job
 - ✓ One day or less is not enough time to do a thorough audit
 - ✓ Typically, depending on the size and complexity of the facility, a thorough team audit usually takes 2 – 5 days



Thoughts on Future Direction

- Provisions should be made for timely, follow-up audits to confirm that companies have taken action against the audit findings
 - ✓ Typically in the 60 – 90 day range; do not let a year go by before the follow-up audit
- A mechanism needs to be found to address the implicit conflict of interest issue
 - ✓ Perhaps fees should be paid directly to the Accreditation Body rather than the Certification Body.
 - ✓ The Accreditation Body then reimburses the Certification Body on a periodic “lump sum” basis for aggregate audits conducted
- Companies must show commitment to aggressively acting on audit findings
- Federal and State regulatory bodies need to strengthen their own inspection programs and depth of knowledge of inspectors and follow-up



Thoughts on Future Direction

- In these tough economic times, the prognosis is not good that meaningful changes in the approach to third party audits will occur
- The industry must realize that without such changes, we will continue to see major foodborne outbreaks arising from facilities that are certified
- Companies must view food safety as a smart investment... no different than investing in sales, marketing, advertising or distribution
 - ✓ A strong, third party certification program, can be a meaningful investment and tangible evidence of company's commitment to food safety if conducted properly



*Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always*



Acknowledgment

I would like to thank Ms. Rena Pierami, from Siliker, Inc. for providing some materials used in this presentation.



Thank you!

Questions?

paul.hall@aivfoodsafety.com

Food Safety Solutions for Your Peace of Mind
Today • Tomorrow • Always

