Roles for Third Parties in Implementing USDA Food Safety and Inspection Service (FSIS)'s Food Safety Process Management Programs

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Roles for Third Parties in Implementing USDA Food Safety and Inspection Service (FSIS)'s Food Safety Process Management Programs[i]

Isadore Rosenthal[ii] and Howard Kunreuther[iii]

This paper's primary objective is the identification of third party roles, and the criteria used to choose third parties that might complement or add value to USDA's Food Safety and Inspection Service's (FSIS) programs aimed at ensuring the safety of commercially processed meat products.

Third party auditors play a major role in implementing a variety of government regulations. After a brief introduction, the paper proceeds to a description of such third party roles in four current US non-food regulations. It then outlines the role of USDA's Food Safety and Inspection Service (FSIS) in ensuring the safety of US meat products and notes the difficulties FSIS faces in obtaining the resources needed to adequately discharge its food safety responsibilities.

The authors then incorporate the lessons learned on the use of third party auditors in non-food regulations into a proposal aimed at addressing the resource problems FSIS faces. Among other things, this proposal calls for the routine use of third party audits -- funded by fees on regulated facilities -- to improve FSIS implementation of the HACCP regulation.

The paper concludes with a discussion of the proposal and the difficulties that FSIS is likely to face in achieving its implementation.

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1. Introduction

Numerous groups within four federal agencies have major food-chain safety related responsibilities (see Appendix 1).

1. Department of Agriculture (USDA)
2. Food and Drug Administration (FDA)
3. Centers for Disease Control and Prevention (CDC)
4. Environmental Protection Agency (EPA)

However, the USDA and the FDA are by far the major regulators of food safety.

Despite these federal agencies' efforts, food supply chains continue to experience many incidents resulting in deaths and serious injuries to members of the public. A recent study on "Health-Related Costs from Foodborne Illness in the United States" estimated these costs to be $152 billion dollars annually.[1]

As Appendix 2 shows, third parties[iv] play a significant role in many business and regulatory programs that are relevant to safety and other issues associated with a wide variety of food and non-food related products and processes.

This paper's primary objective is the identification of third party roles, and the criteria used to choose third parties, that might complement or add value to USDA's Food Safety and Inspection Service's (FSIS) programs aimed at ensuring the safety of commercially processed meat products.

2. Third Party Roles in Implementing Four Non-Food Regulations

A. Boiler and pressure vessel integrity

Major boiler and pressure vessel explosions in the latter half of the 19th century and the early 1900s stimulated the technical, insurance and business communities to explore preventive measures to reduce these risks.

Two milestone events in the development of such preventive measures were:

1. The formation in 1866 of the Hartford Steam Boiler Inspection and Insurance Company[2] following a series of significant boiler explosions in the 1850s, and the 1865 Mississippi River steamer Sultana's boiler explosion which killed over 1,200

[iv] In the commercial area, we use the following description of the parties involved in a transaction:
- First party – The manufacturer and/or supplier
- Second party – The purchaser and/or user
- Third party – An independent entity (person or firm) with no vested interest in the transaction between the first and second party

In the regulatory area, we use the following descriptions of the parties involved in the regulatory process:
- First party – The government regulatory agency
- Second party – The regulated entity
- Third party – The attributes of a third party vary depending on the provisions of the regulation

people. Hartford's boiler insurance policies motivated firms to adopt current 'best safety practices' which included of course those developed subsequently by ASME.

2. The formation of the American Society of Mechanical Engineers (ASME) in 1880,[3] the issuance of ASME's first performance code focused on steam boilers in 1884, and the subsequent issuance of ASME's first full Boiler and Pressure Vessel Standard in the 1914-1915 period.[4]

Currently, regulations aimed at controlling boiler and pressure vessel risks that reference the ASME Boiler and Pressure Vessel Code[5] serve as the major technical basis for 'good practice.' Pertinent provisions of the ASME code have been adopted into law by 50 states, many municipalities in the United States and by all of the Canadian provinces.

Insurance companies play an important role in executing the various state boiler and pressure vessel regulations required inspections. The large majority of these inspections are carried out by persons associated with the facility's insurance company, if the regulated boiler is covered by insurance.[v]

The following language taken from the Maryland regulation regarding inspections is typical of what is found in State statutes:

Division of Labor and Industry Safety Inspection:
Boiler and Pressure Vessel Safety[6],[7]

The Safety Inspection Boiler and Pressure Vessel unit is responsible for the inspection of boilers and pressure vessels used in commercial establishments, places of public gathering, and apartment buildings with six or more units. This responsibility involves ensuring the safe operation of those boilers and pressure vessels by performing periodic inspections and by close monitoring of all repair work. The law also requires that any boiler or pressure vessel that will be installed in Maryland be built to a standardized nationwide construction code, the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code.

The law requires that boilers and pressure vessels are inspected annually or biannually (emphasis added by authors) depending on the type of equipment. Boilers may not be operated without a certificate of inspection. Boiler and pressure vessel installers must notify the Chief Boiler Inspector thirty (30) days prior to installation.

All inspections must be performed by an inspector commissioned by the National Board of Boiler and Pressure Vessel Inspectors. Approximately 270 insurance company inspectors are authorized to conduct inspections (emphasis added by authors) in addition to inspectors on staff with the Division of Labor and Industry. Owners who have obtained insurance coverage on their boilers and/or pressure vessels should expect their insurance company to conduct the necessary inspections (emphasis added by authors).

[v] For example, Tom Healy of the Zurich Insurance company reported that: "[in 2009] I spoke to Allen Platt, the Chief Boiler Inspector in Connecticut, and he indicated that 85 to 90% of all jurisdictional inspections are done by insurance companies. Only 10 to 15% are done by state inspectors."

Inspection Fees:

If the insurance company fails to conduct the inspection on time (emphasis added by authors), or the owner does not have insurance, the inspection will be conducted by a State Deputy Boiler Inspector. Owners will be billed $40 for the first unit inspected at a given location, and $10 for each additional unit inspected at the same location, on the same day. Owners will be billed $10 for the inspection of pressure vessels attached to an air compressor." (Excerpted from United Nations. See Appendix 2, Source 6 of this report.)

It is important to note that facilities cannot operate covered boiler and pressure vessel equipment without an annual inspection certificate and must pay fees for this required boiler inspection. This requirement is also found in the other state boiler regulations that were examined.

There are three requirements for the effective implementation of any safety regulation:

1. Identification of the hazards, practices, processes and equipment subject to the regulation
2. Conformity with an operationally defined set of practices capable of controlling the risks associated the hazards to an "operationally defined" level.[vi]
3. Timely inspections executed by competent inspectors that assess initial and continued conformance with the regulations' requirements.

By and large, the various state boiler and pressure vessel safety regulations satisfy these requirements.

The first of these requirements is satisfied by the fact that U.S. state boiler and pressure vessel safety regulations require compliance with the ASME Boiler and Pressure Vessel Code[8] and this code reflects practitioner thinking on the equipment specifications, operational rules and guidelines required for a boiler and pressure vessel installation to meet generally accepted standards of "good practice."

The second requirement is met by the fact that the state boiler and pressure vessel regulations generally require compliance inspections of covered boiler and pressure vessel equipment upon initial installation, annually and also when any significant changes are made to covered equipment.

The third requirement is met by requiring that inspections be conducted by either:

1. Qualified employees of the boiler and pressure vessel regulatory agency that have met the National Board of Boiler and Pressure Vessel Inspectors competency examination or equivalent state boiler agency requirements.[vii]

Or,

2. Inspectors employed or retained as consultants by boiler insurance companies.

[vi] Operational: "An operational definition is one that people can do business with.... It must be communicable, with the same meaning to vendor as to purchaser, same meaning yesterday and today..." Deming, W.E. (1982). *Out of the Crisis*, pp. 287-289. Cambridge, MA: Massachusetts Institute of Technology, Center for Advanced Engineering Study.

[vii] Becoming a qualified boiler and pressure vessel inspector generally involves successful completion of the National Board of Boiler and Pressure Vessel Inspectors competency examination as well as other requirements of the regulatory agency.

As noted previously, most of the boiler inspections required under state regulations are done by persons associated with "authorized" insurance companies rather than by state regulatory agency employees.

Insurance companies have a substantial stake in ensuring that their employees and agents have good expertise in regard to the risk factors affecting boiler safety because, as Kunreuther[9] notes, they depend on their audit's findings to arrive at competitively priced insurance that distinguishes between good and poor risk firms (a*dverse selection*). They also need effective periodic safety audits to prevent insured firms from behaving more carelessly after they receive coverage *(moral hazard)*.

Not only do insurance company employees and agents have expertise on boiler safety auditing, they also have an obvious self-interest in preventing such accidents since their companies bear some of the resultant losses.

Therefore, it is important to note that inspectors who are employees of boiler insurance companies and also conduct inspections on behalf of a state boiler regulatory agency are not "third parties" as the term is defined in the generic definition of "third party":

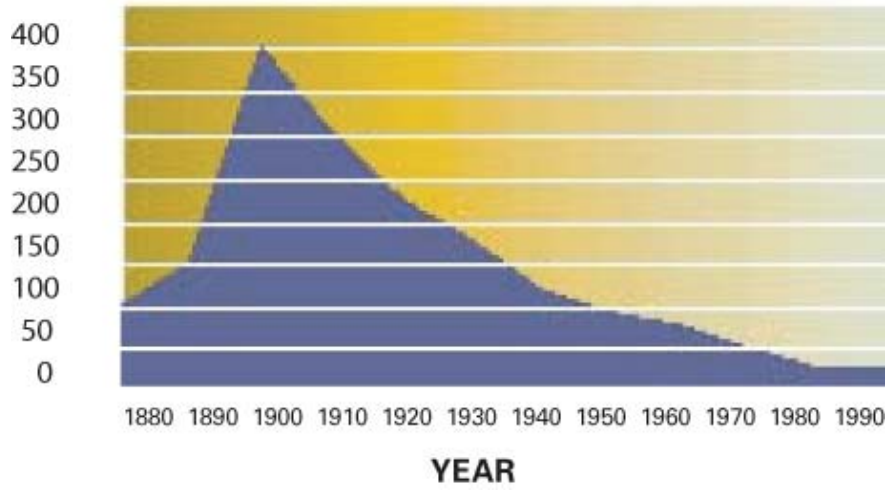
> "Third Party: An independent party that has no personal or direct involvement with the first or second party"

Because of these considerations, one would expect that on average, inspectors associated a boiler insurance company would be biased towards inspection findings that tend toward over-implementation rather than under-implementation of the boiler regulation's accident prevention provisions.

Observations on the effectiveness of boiler and pressure vessel regulations

As Figure 1 shows, boiler and pressure vessel explosions have significantly decreased over time.

Figure 1: NUMBER OF BOILER EXPLOSIONS[10]



However, there are still a very significant number of boiler code violations in the United States each year, as shown in the National Board of Boiler and Pressure Vessel Inspectors "Report on "Violation Findings: Third Quarter 2009."[viii]

Table 1: REPORT OF VIOLATION FINDINGS: THIRD QUARTER 2009[11]

Category	Number of Violations	Percent of Total Violations
Boiler Controls	5,427	32
Boiler Piping and Other Systems	3,543	21
Boiler Manufacturing Data Report/Nameplate	622	4
Boiler Components	2,975	17
Pressure-Relieving Devices for Boilers	2,671	16
Pressure Vessels	1,789	10
Repairs and Alterations	154	1

The authors believe that many factors have contributed to the decrease of incidents shown in Figure 1:

- The quality of the ASME and pressure vessel boiler code
- Improvements in boiler and pressure vessel equipment
- The frequency of required regulatory inspections

However, the most important consideration leading to the noted improvements may be the fact that, because of the benefits boiler insurance firms receive through boiler accident prevention, insurers have been involved and supported development of the ASME code and the various state boiler and pressure vessel regulations. The insurance industry has also succeeded in having most boiler and pressure vessel audits done by their employees or third party inspectors associated with insurers and, as previously noted, this association may bias these auditors towards achieving very strict conformance with these regulations.

The relatively important role that insurance companies play in a number of areas, in regard to controlling risks that they insure, has been discussed in a series of Wharton papers.[12]

[viii] **Summary of Violation Findings**:
Number of jurisdictional reports: 79
Total number of inspections: 198,358
Total number of violations: 17,181
Percent violations: 9

B. The role of the SEC in the preparation of financial reports on public companies

Congress enacted the Securities Exchange Act of 1934[13] in response to the stock market crash of 1929 and the subsequent financial depression. This act created the Security and Exchange Commission (SEC)[14] and gave the SEC primary responsibility for overseeing and regulating the U.S. securities markets, including the authority to prescribe accounting standards that must be followed by public companies[ix] covered by federal securities laws.[15]

The SEC is governed by five commissioners appointed by the president of the United States with the advice and consent of the Senate. Each commissioner is appointed to a fixed five-year term; terms are staggered so that one expires on June 5 of every year. One of the commissioners is designated as chair by the president and no more than three of the five commissioners may be from the same political party. The commission employs financial analysts and examiners, accountants, lawyers, economists, investigators, and other professionals to carry on its responsibilities.

Shortly after its creation, the SEC decided to take a self-regulatory approach, similar to what was later called a management-based approach,[16] to the discharge of its responsibilities for setting up and enforcing accounting and financial standards for public companies and it looked to the private sector for leadership in establishing and improving accounting standards.

The SEC officially recognized the Financial Accounting Standards Board (FASB) in 1973 as the private sector organization for establishing standards for public company financial accounting and reporting.[17] This recognition was reaffirmed in 2003[18] and again in a 2005[19] rule-making notice.

FASB financial accounting and reporting standards are recognized as "generally accepted accounting practices" (GAAP) for purposes of the Federal securities laws. As a result, registrants are required to comply with these standards in preparing financial statements filed with the SEC, unless the SEC provides otherwise.[20],[21] In his testimony to Congress in May 2002, Mr. Herdman, Chief Accountant of the SEC presented an overview of the roles of the SEC and FASB in establishing GAAP.[22]

Publicly traded companies (*first party*) are required to send the SEC (*second party*) many reports on different aspects of their business including an annual 10-K report that details the financial and other aspects of the company's business. An independent Certified Public Accountant (CPA)[x] (*third party*) must certify (*attest*) that the reported financial information is correct, i.e., meets specified requirements and reflects generally accepted accounting standards and practices (GAAP).

[ix] "Public company": a company whose shares can be bought and sold on the stock market. These companies must comply with stringent reporting requirements set out by the Securities and Exchange Commission, including the public disclosure of financial statements.

[x] Certified public account (CPA) is the statutory title of qualified accountants that have passed the Certified Public Accountant Uniform examination.

Publicly traded companies are also required to send annual reports to their shareholders (*second parties*) on or before the company annual meetings to elect directors. It should be noted that a company's publicly available annual report is quite different and much simpler than the required Annual Report sent to company shareholders.[23]

Readers unfamiliar with accounting practices for public firms may not appreciate the complexity of a 10-K report. Perusal of the 10-K form[24] should facilitate understanding of the accounting complexities and malpractices that contributed to the Enron scandal, which will next be discussed.

A large number of company accounting malpractices and frauds emerged in the 2000-2002 period. The scandal at the Enron Corporation was the most notorious of these cases which were collectively labeled by the press as the "Enron Scandals." *Forbes* provides a succinct overview of these various company scandals.[25]

Understanding the nature and cause of the Enron scandal requires an examination of this company's financial malpractices and the reasons these malpractices were not reported by Arthur Andersen, the third party independent auditor of Enron's 10-K report to the SEC.

Enron's financial malpractices centered on the misuse of Special Purpose Entities (SPEs), a complex instrument which was not well understood prior to the Enron scandal even by many accounting professionals.[26]

Enron could have legitimately used SPEs to invest in its own growth through the issuance of debt without the disadvantage of including the additional debt on their consolidated financial statements, provided the SPE was used in accordance with GAAP and the action was transparent to users of financial statements. However, Enron did not meet this requirement: It used SPEs to hide increases in its corporate debts and also give "off the record" compensation to officers of the company. Gillan and Martin provide a detailed description of this misuse of SPE's by Enron.[27]

In retrospect, it is clear that Enron's board of directors could have detected Enron management's malpractices and by law should have attempted to prevent them, but did not do so.[28] The "Report of Investigation by the Special Investigative Committee of the Board of Directors of Enron Corp" dated February 1, 2002, noted that:

> "Overall, Enron failed to disclose facts that were important for an understanding of the substance of the transactions. The Company did disclose that there were large transactions with entities in which the CFO had an interest. However, Enron did not adequately disclose the CFO's actual or likely economic benefits from these transactions, the purposes of these transactions or the likely impacts of these complex arrangements. The disclosures also asserted without adequate foundation that the arrangements were comparable to arm's-length transactions. We believe that the responsibility for these inadequate disclosures is shared by Enron Management, the Audit and Compliance Committee of the Board, Enron's in-house counsel, Vinson & Elkins, and **Andersen."** (Emphasis added)"[29]

Andersen was the independent certified public accounting firm that certified that Enron's annual 10-K reports were prepared in conformance with applicable law and GAAP before and during the period the Enron scandal unfolded.

However, the literature is clear, at least in retrospect, that Andersen's certifications of Enron's annual 10-K reports were 'clearly' not justified and that Andersen's objectivity had been compromised, unconsciously or consciously by its desire to build and keep the very profitable consulting service business that it had with its audit clients.

Gillan and Martin made the following observation in regard to the 'independence' required of Andersen as a third party auditor:

> *"Andersen served as both Enron's internal and external auditor. Essentially, when Andersen performed its external audit it was reviewing its own work. For example, Andersen advised Enron on the structure of many its SPEs, received consulting income for doing so, and audited those transactions. This leads to the third challenge to auditor independence – auditors accepting consulting engagements with audit clients have long been recognized as a potential source of conflict of interest problems …. During 2000, Enron paid Arthur Andersen total fees of $52 million, including $25 million for the audit, $14 million for work arguably connected to the audit (Andersen's CEO testified before congress that the work can "only be done by auditors"), and $13 million for other consulting. These fees made Enron one of Andersen's largest clients, and certainly one of the largest clients for its Houston office."*[30]

A recent study by the Centre for Financial Market Integrity (CFA) essentially concluded that what had occurred at Andersen was generally true for the whole industry:

> *"Over a period of decades, the historical trust between investor and auditor did eventually break down. Because of accounting firms' reliance on their audit clients for revenues (derived from both audit and, more important, non-audit or consulting engagements), auditors came to identify with the managers of the companies they audited, rather than with the shareowners and other investors on whose behalf the audit requirement was established. This reliance on clients for revenues began to subvert the self-regulatory process as the auditing profession failed to ensure that investors had full and fair disclosure. The loss of confidence by the investing public ultimately resulted in a decline of influence and self-regulatory responsibility"*[31]

Kroger,[32] Barrett,[33] Cunningham,[34] Moore[35] and others arrived at conclusions similar to those the paper previously noted in regard to the compromised integrity of many of the third party auditors of Public company financial reports.

One of the aftermaths of the Enron scandals was enactment of the Sarbanes-Oxley Act of 2002 (SOX),[36,37] also known as the Public Company Accounting Reform and Investor Protection Act of 2002, established new or enhanced standards of practice for all U.S. public company boards, management, and public accounting Firms. It contains eleven sections that address a wide range of topics such as criminal penalties, auditor independence, corporate governance, internal controls and financial disclosure. SOX also require the SEC to implement rulings on requirements needed to comply with the new law.[38]

Examination of the provisions of SOX[39], show that Title I, Title II and Section 302 of Title III of the SOX law are of particular importance to maintaining the integrity of role of third party accountants:

Title I - Public Company Accounting Oversight Board. Establishes the Public Company Accounting Oversight Board (PCAOB) to:

(1) Oversee the auditing of public companies that are subject to SEC securities laws;

(2) Establish audit report standards and rules for Public companies; and

(3) Inspect, investigate, and enforce compliance on the part of registered public accounting firms, their associated persons, and certified public accountants.

Title II - Auditor Independence. Amends the Securities Exchange Act of 1934 to prohibit an auditor from performing specified non-audit services[40] contemporaneously with an audit (auditor independence). Requires pre-approval by the audit committee of the issuer for those non-audit services that are not expressly forbidden by this Act.

Section 302 of Title III, Instructs the SEC to promulgate requirements that the principal executive officer and principal financial officer certify the following in regard to the company's periodic financial reports:

(1) The report does not contain untrue statements or material omissions;

(2) The financial statements fairly represent the financial condition and results of operations; and

(3) That officers responsible for putting internal financial controls in place receive all material information regarding the issuer and consolidated subsidiaries.

Title III also requires senior corporate officers to certify that auditors and the audit committee of the board of directors have received;

(1) Periodic financial reports that do not contain untrue statements or material omissions

(2) All material information regarding the issuer and consolidated subsidiaries

(3) All material information on significant internal control deficiencies and frauds that involve staff who have a significant role in the issuer's internal controls.

As noted, SOX also created the Public Company Accounting Oversight Board (PCAOB).[41] PCAOB acts as a private-sector regulator with responsibilities in regard to overseeing, regulating, inspecting, and disciplining accounting firms in regard to their role as third party auditors of public company financial statements. PCAOB was also authorized to set and impose fees on Public accounting firms in order to fund its operations.[42] The SEC was given overall responsibility for overseeing PCAOB's performance, its annual budget and approval or disapproval of any auditing rules put forward by PCAOB.

Observations on the integrity of financial reports on public companies

Numerous investigations following the Enron accounting scandals confirmed two widely held beliefs:

1. Company executives' self-interests could lead them to falsify company financial information reported to shareholders and public members of the company's board of directors.
2. The objectivity (independence) required of Certified Public Accountants accredited to verify the 10-K reports of a public company was often not monitored effectively by either the organizations that accredited them or the board of directors of the company that employed them.

Provisions of SOX addressed both of these issues by:

1. Requiring company officers to certify that measures were in place that ensured that they, the board of directors and the corporate audit committee received all material financial information pertinent to their respective responsibilities.
2. Creating the Public Company Accounting Oversight Board (PCAOB) to verify that CPAs adhered to "generally accepted good practice" requirements. PCAOB was funded by fees it imposed on regulated CPAs.[43]

It will be interesting see whether the benefits and costs of PCAOB lead the SEC or other regulatory agencies to justify similar command and control measures when society relies on a third party to confirm that that a high hazard company operation does not impose significant financial risks on the public.[xi]

Currently there are widely differing views on the value of both the Sarbanes-Oxley act[44],[45] and PCAOB.[46]

Postscript on the integrity of financial reports on public companies

The current 2008-2010 financial crisis has many similarities with the one following the 2001 Enron scandals which were triggered by the disclosure of Enron's abuse of relatively obscure investment practices and instruments (Special Purpose Entities).

As the *New York Times* noted:[47]

> *"This was the year that many readers — not to mention financial reporters — learned what C.D.O., M.B.S. and SIV stood for, 2008 could be the year of C.D.S. and C.L.O. (For those who came in late, those abbreviations from 2007 are shorthand for collateralized debt obligations, mortgage-backed securities and structured investment vehicles. The new ones are credit default swaps and collateralized loan obligations — a special kind of C.D.O. backed by corporate loans.)*

[xi] For example, in the recent 2008-2009 financial crisis companies such as AIG, Goldman Sachs, and Bank of America were bailed out by the government because they were deemed to be "too big to fail."

This *New York Times* article also makes the following observations:

> *"But if the credit insurers turn out to have had inadequate reserves, what are we to make of the credit default swap market? Mr. Seides calls it "an insurance market with no loss reserves," and points out that $45 trillion in such swaps are now outstanding. That is, he notes, almost five times the United States national debt."*
>
> *"The corporate credit market is vastly larger than the subprime market, and there are plenty of dubious loans outstanding that probably could not be refinanced in the current market. If some of those companies run into problems, defaults could soar and fears about C.L.O. valuations and C.D.S. defaults could spread long before there are large actual losses on loans."*
>
> *"It was the greatest credit party in history, made possible by a new financial architecture that moved much of the activities out of regulated institutions and into financial instruments that emphasized leverage over safety. The next year may be the one when we learn whether the subprime crisis was a relatively isolated problem in that system or just the first indication of a systemic crisis."*

Another *New York Times* article deals with SEC's role in regard to the developing credit crisis and notes:[48]

> *"Because it is a relatively small agency, the S.E.C. tries to extend its reach over the vast financial services industry by relying heavily on self-regulation by stock exchanges, mutual funds, brokerage firms and publicly traded corporations."*

Other excerpts from the same article also reported that Mr. Cox, chairman of the SEC now recognized the SEC's reliance on self-regulation was misplaced:

> *"The last six months have made it abundantly clear that voluntary regulation does not work," he said in a statement. "The program was fundamentally flawed from the beginning, because investment banks could opt in or out of supervision voluntarily. The fact that investment bank holding companies could withdraw from this voluntary supervision at their discretion diminished the perceived mandate of the program, and weakened its effectiveness," he added.*
>
> *Mr. Cox and other regulators, including Ben S. Bernanke, the Federal Reserve chairman, and Henry M. Paulson Jr., the Treasury secretary, have all acknowledged general regulatory failures over the last year. Mr. Cox's statement on Friday, however, went beyond that by blaming a specific program for the financial crisis — and then ending it.*
>
> *On one level, the commission's decision to end the regulatory program was somewhat academic, because the five biggest independent Wall Street firms have all disappeared."*

The failure of the SEC's self-regulatory approach to controlling credit risks raises many questions regarding whether it is appropriate to use self-regulatory measures,[49] if:

- The risks are not transparent
- Mismanagement of the risks can lead to significant societal losses
- Accepting a particular class of credit risks (e.g., subprime mortgages) leads to relatively high immediate payoffs for some of the firm's agents, whereas the likelihood of losses which may reflect on these agents' judgment are visualized as small or unlikely to occur during these agents employment with the firm.

In concluding this discussion, it is interesting to examine a recent *New York Times* article on "In Lehman's Demise, Some Shades of Enron."[50] This article notes:

> *"The bankruptcy examiner's report filed by Anton R. Valukas on the 2008 demise of Lehman Brothers discusses some accounting gimmicks that are eerily reminiscent of how Enron tried to prop up its balance sheet back in 2001 before it collapsed.*
>
> *Both companies appear to have played right along the edge of properly accounting for transactions designed to make them appear much stronger than they turned out to be, becoming steadily more aggressive as they teetered on the brink of ruin."*

The authors believe that the failure to detect and prevent such Lehman accounting malpractices reflects poorly on the Public Company Accounting Oversight Board (PCAOB).

C. Mechanical press safeguarding

OSHA issued the Mechanical Power Press Standard, (29 CFR 1910.217) in 1971.[51] This standard was in large part based on the ANSI voluntary consensus standard B11.1-1971, "Safety Requirements for the Construction, Care, and Use of Mechanical Power Presses."

The 1971 Standard incorporated the ANSI standard's restrictions on the use of presence sensing devices:

> "The 1971 ANSI standard permitted presence sensing devices (PSD) to be used as a guard, but it did not permit the PSD to initiate (actuate) the stroke of the press when the PSD senses that the employee has fed the press and removed the employee's hands and arms from the point of operation." This restriction in effect banned primary reliance for operator safety on devices that sensed whether any part of an operator's body was in a power press danger zone (*emphasis added by authors*). If a power press is equipped with a presence sensing device (PSD), the press cannot stamp if an operator is reaching through a light curtain to load a part into a machine."

Despite the enactment of the 1971 Mechanical Power Press Standard, injuries associated with operation of mechanical power presses continued to be unacceptably high. For example, NIOSH concluded in 1987 that:

> "Even though there is an existing OSHA standard that addresses construction and operation of mechanical power presses, injuries and amputations among press operators are still occurring with alarming frequency. In many cases, these injuries occur when the press is inadvertently activated while the operator's hands are in the operating zone of the press."[52]

In effect then, the 1971 Mechanical Power Press Standard had not reduced worker injuries to the extent that OSHA had hoped for.

After several major studies of what might be done to further reduce mechanical press injuries, rounds of public comments, a review of European experience and a public hearing, OSHA was convinced that permitting the use of pressure sensing device initiation (PSDI) on mechanical power presses would substantially improve worker protection.

Acting on this conviction, OSHA issued a modification of its 1971 rule in 1988 that allowed use of a PSD device as a primary safety measure on mechanical power presses. The New Mechanical Power Press Standard (1988 Regulation) permitting the use of PSDI was issued on March 14, 1988.[53] It contained an added paragraph (h) which required among other things that the safety of a PSDI mechanical power press must be validated by an OSHA-certified third party ("validator") before it is placed into operation and must also be recertified as "safe" annually.

More specifically, paragraph (h) of the 1988 OSHA standard led to the requirement that:

> The manufacturer shall evaluate and certify, and the OSHA-recognized third-party validation organization shall validate, (emphasis added) the design and operation of the safety system has the following attributes:
>
> (1) No single failure points may cause injury,
>
> Or
>
> (2) Redundancy, comparison and/or diagnostic checking, exist for the critical items that may cause injury, and the electrical, electronic, electromechanical and mechanical parts and components are selected so that they can withstand operational and external environments. The safety factor and/or derated percentage shall be specifically noted and complied with.

After the 1988 Regulation was issued, OSHA awaited applications from third parties interested in becoming a validator under the provisions of the Regulation. No applications were submitted and therefore, the regulation could not be implemented. It soon became apparent that the principle reason for this failure to enlist third party validators was that even if a power press conformed with the provisions of the 1988 regulation, it would still not meet the validation requirement that "no single failure or single operating error" will cause injury to personnel from a "point-of-operation hazard."

In fact, taken literally, there was no way that a commercial mechanical power press could meet such a safety requirement since as long as a hazard capable of causing injury exists, there will be some probability that one or more injuries will occur over time.

Third party validators apparently were concerned about their liability if they validated a process as safe and subsequently a very low probability injury occurred despite the fact that the process they validated:

1. Conformed to the provisions of the 1988 Regulation
2. Met good or even best practices
3. Process risks were as "as low as reasonably practicable" (ALARP).[54]
4. The risk that led to the injury was in the general range of OSHA acceptable risks

OSHA became aware of these third party liability concerns shortly after the 1998 Regulation was issued and recognized the need to deal with them. However, accomplishing the changes OSHA felt were needed to deal with third party liability concerns involved a complex process. The initial results of this process became apparent in 2002 when OSHA filed a "Notice of a Regulatory Flexibility Act Review of Presence Sensing Device Initiation of Mechanical Power Presses."[55]

OSHA concluded its Flexibility Act Review in May of 2004[56] and published the findings of this review in the Federal Register on June 8, 2004.[57] The May 2004 Report discusses the costs of mechanical power presses injuries in Chapter 1, "Previous Characterization of Industry and Impacts":

> *"In its 1988 rulemaking, OSHA analyzed the impact of paragraph (h) on small entities as part of its economic impact analysis. At that time, OSHA estimated that approximately 73,000 employees would be affected by the standards. These employees are primarily punch and stamping press operators and job and die setters. OSHA estimated that 40 percent of the former group and 20 percent of the latter were operating mechanical power presses. These operators are employees in metal fabrication industries and the automotive industry."*
>
> *"OSHA estimated that PSDI would increase productivity an average of 24.3 percent per press. On a national level, OSHA estimated that the use of PSDI would save industry about $162 million a year. OSHA estimated that cost of installing PSDI systems and having them certified would be between $49 million and $77 million by 1991. OSHA also estimated that by 1996, 2,500 new presses would be equipped with PSDI, producing additional productivity savings. The total net annualized savings were estimated to be between $100 million and $129 million. Because of the cost savings, OSHA determined that the standard would not have a significant economic impact on small entities."*

Section 4.1 "Third Party Validation" of the May 2004 OSHA report discusses OSHA's findings in regard to the problems encountered in implementing the paragraph (h) of the 1988 Regulation:

> *4.1 Third-Party Validation*
> *Whatever other issues there may be with paragraph (h), the main reason that the PSDI provisions have not been implemented is that no organization has come forward to serve as a third party validator. OSHA originally adopted third-party validation for the following reasons:*
>
> - *A similar approach was used in Germany and Sweden, and many experts believed it would work in the U.S.*
> - *OSHA-approved Nationally Recognized Testing Laboratories (NRTLs), which are third-party product certifiers, perform activities similar to that contemplated for a validator, and it was expected that NRTL's would apply to be validators. The standard was also designed to allow industry organizations to establish semi-independent entities to serve as validators.*
> - *The fees collected for annual recertification of PSDI systems were assumed to be profitable enough for the validating organization to justify the required investments in equipment and training.*
> - *Liability would be limited because the employer or assembler would certify compliance; the third party would only validated the certification.*
> - *Many experts commented that the rule would work.*

Each of the industry sources[58] interviewed provided the same set of comments on why no organization pursued OSHA approval as a third party. These comments noted that:

- *The standard requires the third party to validate that no single failure will result in an injury." Given that a mechanical power press has a single brake, a single clutch, and a single transmission, it is impossible to state that a single failure will not result in an injury. A catastrophic mechanical failure could, and occasionally has, resulted in injuries. The only machine guard that prevents operator injuries in this case is the automatic pullback device. Pullbacks, like the other non-PSD guards, do not protect non-operators who are sometimes the ones injured. Consequently, no third party (or original equipment manufacturer (OEM)) would be willing to make the validation that OSHA requires.*
- *Any organization that served as a third party would be taking on considerable potential liability; sharing with the OEM exposure should an injury occur. Because injuries continue to occur and lawsuits against OEMs are not uncommon, most testing organizations do not want to take the risk.*
- *Third-party testing organizations usually test to a specific test standard that covers a particular kind of item (e.g., hardhats, electrical wires). Paragraph (h) requires the testing of the press, the PSD, and the control system, plus the installation. Combined with liability concerns, this type of validation raises substantial concerns about the ability of organizations to do the validation."*

In essence, these May 2004 findings are similar to what OSHA and many practitioners already believed and had expressed many years earlier.

On June 4, 2007, OSHA issued an Advance Notice of Proposed Rulemaking which reviewed what had essentially been disclosed in its May 2004 Report, stating that "OSHA intends to update the mechanical power press standard to be consistent with ANSI B11.1–2001 or something similar" and then made the following request:

> *"OSHA is seeking comments on whether and how the mechanical power presses standard should be amended, including whether the requirements pertaining to the use of PSDI systems should be revised and whether the scope of the standard should be expanded to cover other types of presses."*[59]

D. EPA's Process Safety Standard (RMP)

Public concerns, aroused after a series of major accidents[60] in the 1970-1990 time periods, led both OSHA and EPA to issue process safety regulations.

In 1992, OSHA fulfilled its CAAA Section 304 requirements in regard to process safety by issuing OSHA standard 29 CFR 1910.119, "Process Safety Management of Highly Hazardous Chemicals" (PSM).[61] The PSM standard focused on preventing and mitigating process accidents that might impact people and property within the process facility.

EPA fulfilled its obligations in 1996, by issuing a regulation titled "Accidental Release Prevention Requirements: Risk Management Programs under the Clean Air Act, Section 112(r) (7) Rule (RMP Rule)."[62] (This regulation focused on preventing and mitigating process accidents that might impact the environment, people or property

outside the process facility.[xii] As discussed below, the EPA Rule also incorporated the integrated prevention program in OSHA's PSM by reference.)

The RMP Rule requires covered facilities to have an integrated prevention program with the following six required elements:[63]

- An off-site consequence analysis that evaluates specified potential release scenarios, including worst-case and alternative scenarios
- A 5-year history of all specified types of accidental releases of regulated substances from RMP covered processes
- An integrated risk management prevention program
- An emergency response program
- A risk management plan (RMP), revised at least once every five years, that summarizes and documents these activities for all covered processes"
- An overall management system to supervise the implementation of these program elements

It should be noted that the RMP Rule is a management-based regulation[64] and does not "operationally"[65] detail the specific technical, and performance practices that must be in place in order for a covered process to be compliant with the requirements of each of its six RMP regulation elements.

The RMP Rule's "integrated prevention program" basically incorporates the prevention program in the OSHA PSM regulation by reference, as shown in Table 2 taken from the RMP Rule.

[xii] The RMP Rule prescribes the character and magnitude of accidents that must be reported to EPA in a facility's five-year accident reports.

Table 2: SUMMARY OF PROGRAM 3 PREVENTION PROGRAM (40 CFR PART 68, SUBPART D)[66]

SECTION	TITLE	OSHA PSM REFERENCE
§ 68.65	Process Safety Information	PSM standard § 1910.119(d).
§ 68.67	Process Hazard Analysis (PHA)	PSM standard § 1910.119(e).
§ 68.69	Operating Procedures	PSM standard § 1910.119(f).
§ 68.71	Training	PSM standard § 1910.119(g).
§ 68.73	Mechanical Integrity	PSM standard § 1910.119(j).
§ 68.75	Management of Change	PSM standard § 1910.119(l).
§ 68.77	Pre-Startup Review	PSM standard § 1910.119(I).
§ 68.79	Compliance Audits	PSM standard § 1910.119(o).
§ 68.81	Incident Investigation	PSM standard § 1910.119(m)
§ 68.83	Employee Participation	PSM standard § 1910.119(c).
§ 68.85	Hot Work Permit	PSM standard § 1910.119(k).
§ 68.87	Contractors	PSM standard § 1910.119(h).

Two factors posed major challenges to both Industry and EPA as they undertook to discharge their responsibilities under the RMP Rule:

1. The RMP Rule is a "management-based regulation"
2. Process accidents covered under the RMP Rule are low-probability events

Examination of these factors illuminates why industry's implementation of the RMP Rule and EPA's monitoring of industry's compliance with the Rule's provisions are difficult tasks.

Coglianese and Lazar describe management-based regulations as follows:

> *"Yet missing from the traditional emphasis on technology-based and performance-based regulation has been much systematic attention to a third type of regulatory instrument that we call 'management-based regulation.' Management-based regulation does not specify the technologies to be used to achieve socially desirable behavior, nor does it require specific outputs in terms of social goals. Rather, a management-based approach requires firms to engage in their own planning and internal rulemaking efforts that are supposed to aim toward the achievement of specific public goals."* [67]

They also note that:

> *'"What we call management-based regulation resembles what others have called "enforced self-regulation" (Braithwaite 1982)[68], "mandated self-regulation" (Bardach & Kagan 1982)[69]; (Rees 1988)[70], "reflexive" regulation (Orts 1995)[71] or "process-based" (Gunningham & Grabosky 1998)[72] and "systems-based" (Gunningham 1996)[73]; Gunningham & Johnstone 1999)[74] standards. We use the term management-based regulation to encompass a range of processes, systems, and internal management practices that government requires of private firms. Although this basic approach has been noted and described by socio-legal scholars of regulation, virtually no attention has been given to management- based approaches in the broader literature on regulatory instrument choice."*

EPA implicitly recognized that the RMP regulation was a management-based regulation when it noted[75] that:

> *"Many part 68 requirements do not specify exactly what you must do to meet them; instead, they provide you with flexibility to develop an approach that makes sense for your facility. This allows you to tailor your program to fit the particular conditions at your facility. The degree of complexity required in a risk management program will depend on the complexity of the facility. For example, the operating procedures for a chemical distributor are likely to be relatively brief, while those for a chemical manufacturer will be extensive. Similarly, the length of training necessary to educate employees on such procedures will be proportional to the complexity of your operating procedures. And while a facility with complex processes may benefit from a computerized maintenance tracking system, a small facility with a simpler process may be able to track maintenance activities using a logbook.*
>
> *There is no one "right" way to develop and implement a risk management program. Even for the same rule elements, your program will be different from everyone else's programs (even those in the same industry) because it will be designed for your specific situation and hazards — it will reflect whether your facility is near the public and sensitive environmental areas, the specific equipment you have installed, and other relevant factors".*[xiii]

Clearly, there is agreement that the RMP Rule is a management-based regulation and as such, it does not operationally specify exactly what must be done to achieve "compliance."[76] This lack of specificity has great benefits because it allows covered companies flexibility in achieving compliance. However, this flexibility can also lead to legitimate disagreements on whether a facility's actions in meeting a particular RMP Rule specification are appropriate. In addition to being compliant with the Rule's specific provisions, the RMP Rule also mandates that covered processes must be designed and operated in compliance with "Recognized and Generally Available Good Engineering Practices" (RAGAGEP).

Meeting these RMP Rule mandates requires that a facility's covered processes be designed, constructed and operated with staff capable of understanding whether their actions are compliant with the Rule's provisions including RAGAGEP. This is not easy

[xiii] In essence, a performance-based regulation with limited specifications is a "management-based regulation" since it also does not operationally specify exactly what must be done to achieve compliance.

to ascertain and can only be accomplished by very competent facility staff. The same type of challenges face regulatory agency auditors charged with ascertaining whether a process is being operated in compliance with the RMP Rule's requirements.

To its credit, the chemical industry recognized these challenges even before the RMP Rule was promulgated and in 1985 it created the non-profit Center for Chemical Process Safety (CCPS)[77] under the sponsorship of the American Institute of Chemical Engineers (AIChE). CCPS published its first process safety guideline book, *Guidelines for Hazard Evaluation Procedures*, by 1990 and has continued its work on process safety. It now has a catalog of over 100 books and products. CCPS technical guidance products do not eliminate the compliance challenges associated with the management-based nature of the RMP Rule, but they do make it easier for diligent firms to come into compliance with the Rule if they chose to make the considerable effort required to translate CCPS guidance into practice.

Fortunately, process accidents covered under EPA's RMP rule present relatively low probability (LP) risks. Unfortunately however, as the literature shows, individuals tend to postpone correction (or even recognition) of LP risks even if they have the potential for high consequences (HC).[78,79] Many (most?) facilities attention to the prevention of LP-HC events, such as RMP process accidents tends to decay over time, particularly if there has been no recent industry accident severe enough to attract significant public, regulatory agency or company shareholder attention.[80]

After the adoption of EPA's RMP Rule in 1996, the Wharton Risk Management and Decision Processes Center[81] undertook a project aimed at studying how the benefits of the RMP rule might best be realized and its foreseeable deficiencies minimized by the way the Rule was implemented by covered facilities and enforced by EPA. This project (Wharton RMP Project) involved a multiyear series of "off the record" presentations and discussions attended by representatives of prominent companies, U.S. and state regulatory bodies, technical professional societies, insurance companies and consulting firms.

One of the issues addressed by the Wharton RMP Project was how the responsible Regulatory agencies could effectively audit covered facilities compliance with the RMP Rule's provisions. The RMP Rule called for such audits by EPA or those States which obtained a delegation to enforce the RMP Rule such as Delaware, New Jersey, California and Nevada.

However, while the Rule required that facilities must audit their compliance with the RMP Rule at least every three years, it did not specify the protocol that facilities must use to accomplish such audits. Moreover, the Rule was silent on the frequency or character of EPA's audits of RMP facilities compliance with the Rule. Clearly, if EPA conducted very frequent audits with unjustified, inappropriately restrictive findings, this would be a problem for industry. On the other hand, if EPA failed to put an effective RMP audit program in place, this failure would put the public, employees, and/or insurance companies at unjustified risk

This last consideration arose as a result of concerns about whether EPA or a delegated State agency had both the funding and qualified auditors needed to execute an effective audit program. The project's participants felt that this problem warranted special attention and they developed a plan for evaluating the feasibility, costs and efficacy of using third party auditors that would be 'certified' by the regulatory agency having responsibility for a facility's RMP Compliance, but paid for by the company being audited.

There were a variety of different reasons that the Study's participants may have had for exploring the use of third party auditors to support implementation of the RMP Rule:

1. It appeared unlikely to them that RMP regulatory agencies had, or would be provided with the resources required to execute an adequate RMP audit program.[82]
2. Insurance companies and consultants may have seen third party audits as a business opportunity.
3. As a matter of principle: the cost of establishing whether a risk imposed by a facility on the public met societal requirements should be borne by the facility.
4. Use of qualified third party auditors would lead to improved facility RMP audits.

The participants in this third party audit project (third party team) included EPA's Chemical Emergency Preparedness and Prevention office (CEPPO), the Wharton School, Delaware's Dept. of Natural Resources (DNREC), EPA Region III, private companies subject to the RMP rule, insurance companies, trade and professional associations, as well as other government agencies and consultants.

In August 2000, CEPPO described its participation in the RMP third party audit project as follows:[83]

> *"EPA Region III has been collaborating on a research effort with The Wharton School and other stakeholders to explore the possibility of using third-parties, such as insurance companies and safety consultants, to audit small business compliance with the RMP rule. A few third party audits are being conducted as a pilot in Pennsylvania. EPA Region III has selected and trained third party auditors who will conduct document reviews and on-site visits and summarize their findings in audit reports. As part of the pilot, EPA inspectors will conduct separate audits to verify the accuracy and thoroughness of the third-party audits and to get feedback from the participating facilities about the experience. The results of the pilot project will be shared with insurance companies, trade associations, public interest groups, and regulatory agencies."*

After a series of discussions, the third party project team decided to explore the use of independent third party RMP auditors by conducting two pilot tests that would be executed by EPA's Region III and Delaware's Dept. of Natural Resources and Environmental Control.

Delaware, which had obtained delegation to implement the EPA RMP Rule, was selected as one of the locations for carrying out the independent third party audit trials. Delaware had considerable experience in auditing process safety performance under a state regulation covering chemical process risks that had been in place since 1990. This

allowed comparison of the quality of trial RMP audits conducted by project third party auditors with the quality of audits previously obtained by DNREC auditors under the state regulation.

Pennsylvania was the second location selected for the third party audit trials. Unlike Delaware, Pennsylvania had no RMP type process safety regulation in place prior to adoption of the U.S. RMP Rule. EPA (Region III) agreed to sponsor the audits conducted by the project's third party auditors and then evaluate the results of these audits against their own findings.

The third party auditors used by DNREC for the experiment in Delaware were selected by DNREC from a list of 50 third party candidates supplied to DNREC by the Wharton Risk Management Center. DNREC selected three inspectors from an insurance company, two from engineering firms, and three from government and small business. Similarly, the third party auditors selected by EPA Region III for the experiment in Pennsylvania were also selected from a Wharton Risk Center list of third party candidates. EPA selected three auditors from three different insurance companies, two from the City of Philadelphia, and one from a testing laboratory.

DNREC and EPA Region III trained the candidate third party auditors for two days and then assigned them to audit chosen chlorine and ammonia facilities in Delaware and Pennsylvania. In essence, the results by the chosen third party auditors were similar to those obtained by DNREC and EPA Region III in their own inspections of the chosen chlorine and ammonia facilities.

In both Delaware and Pennsylvania, Wharton researchers found that the owners and operators of facilities were open to third party inspections provided they yielded commensurate benefits.

More specifically, facility owners said they would be open to such third party audits if:

1. EPA or a state regulatory agency gave them a seal of approval based on the results of the inspection, or
2. There were economic benefits from their insurance companies for undertaking such audits, and
3. The community viewed positive results from an inspection as a signal that the firm was operating safely.[84]

Larry Collins of the Zurich Insurance company and a diverse group of other participants summarized the nature and results of these test third party audits of RMP compliance at 21 chemical facilities in Delaware and Pennsylvania and reached the following findings and conclusions:

RMP Third-Party Audit Pilot Project[85]

The idea of using third parties as independent auditors was extensively investigated through a series of roundtable meetings at the University of Pennsylvania's Wharton School. These meetings explored the use of third-party auditors and led to two field pilot tests of the concept. Participants included CEPPO, the Wharton School, Delaware's Dept. of Natural Resources and Environmental Control, EPA Region III, loss prevention representatives, private companies, trade and professional associations, other government agencies and consultants. The pilot experiment was conducted in two phases during 1999 and 2000. In these studies, third-party auditors were used to evaluate RMP compliance at 21 chemical facilities in Delaware and Pennsylvania. Through the experiment, EPA wanted to test the concept of third-party inspectors for RMP compliance audits in two different regulatory environments.

Following a two-day training program, Phase I of the pilot was conducted in Delaware, where a state level accident prevention law similar to section 112(r) already existed. Phase II was conducted in Pennsylvania, which had no state level law or RMP delegation

These studies participants addressed several questions:

- *Could third parties conduct comprehensive risk management program audits?*
- *Would these audits be as rigorous as audits conducted by government inspectors?*
- *What background and experience would best prepare a third party to conduct RMP audits?*
- *What additional training would be necessary to prepare prospective third-party auditors?*
- *How would facilities react to the presence of auditors? Would facilities see value in the audit?*
- *How much time would an audit take?*
- *Would facilities in states without previous accident prevention laws in place be less compliant with the RMP rule and, therefore, more difficult for a third party to audit?*

The two pilot projects established the following important findings:
1) Third parties could successfully conduct compliance audits at RMP facilities with adequate rigor;
2) Previously existing state regulatory environment had little effect on the ability of third parties to conduct adequate audits;
3) Facilities reacted favorably to the presence of third-party auditors and found third-party audits to have value.

The pilot studies and roundtable meetings also provided valuable insight into other critical issues, such as necessary training and experience for third party auditors; costs; incentives needed to encourage facilities to volunteer for an audit; and the potential role of insurance companies in third-party audits.

From an insurance industry perspective, the pilot studies were also successful in establishing that:

- *Prior auditing experience in other areas translates well into the environmental arena.*
- *Auditor training was the key to the success of the pilot studies.*
- *The report format used, while successful during the pilot, might be too 'extensive' for use on an ongoing basis. Some reports were more than 100 pages for simple assessments.*
- *Client cooperation was key. Without their active participation, successful interviews and surveys could not be completed."*

Robert Barrish, an employee of DNREC and a participant in the project, essentially agreed with Collins' conclusions and noted that:

> *"The third party auditors were able to identify both areas of exceptional performance and areas that required improvement. The auditors felt that the audit took longer to accomplish than they expected. Some auditors felt that working together on their first audits had some advantages.*
>
> *The auditors occasionally accepted performance that the implementing agency would not have accepted. A disagreement over the degree of a potential deficiency is common, as this is a performance-based regulation that has limited specifications. This type of rule is open to interpretation and acceptable compliance can vary depending on the observer. We feel this level of performance is much the same as any new implementing agency might experience."*[86]

James Belke, CEPPO's participant in the Wharton program also concurred with Collins and Barrish and noted that:

> *"In summary, the experiment conclusively demonstrated that third parties could successfully conduct compliance audits at RMP facilities with adequate rigor, that the previously existing state regulatory environment appeared to have little effect on the ability of third parties to conduct adequate audits, and that facilities reacted favorably to the presence of third party auditors and found third party audits to have value."*,[87]

Clearly a diverse group of experienced stakeholders concluded that third party auditors were capable of executing effective audits of covered company compliance with the RMP Rules requirements.

During the time period that the Wharton project team was evaluating the third party audit option, the resources available to EPA were decreasing and Walter Frank noted:

> *"Based on input from states and EPA regional offices administering the RMP rule, EPA has effectively concluded that RMP regulators will not have sufficient resources to ensure industry compliance with the RMP rule."*[88]

EPA posted the abstract of a proposed regulation, aimed at promoting the use of third party RMP auditors, on December 2001. The abstract read as follows:

> *"This action establishes requirements, incentives, and procedures for third party audits of Risk Management Plans (RMPs) under 40 CFR part 68 that would reduce the need for, and thus the incidence of, government audits of RMPs submitted by facilities that volunteer for such an audit. In this context, a third party is someone not employed by either an RMP-regulated facility or a government agency responsible for implementing the RMP program (implementing agency). In the preamble to the final Risk Management Program rule, EPA endorsed the concept of using third parties to assist in rule compliance and oversight (61 FR 31705), provided that any such proposal: not weaken the compliance responsibilities of facility owner/operators; offer cost savings and benefits to the industry, community, and implementing agencies that significantly exceed the cost of implementing the approach lead to a net increase in process safety, particularly for smaller, less technically sophisticated facilities; and promote cost-effective agency prioritization of oversight resources. However, no specific criteria or requirements were specified in the RMP rule to regulate the activities of facilities, implementing agencies, or third parties with respect to third party assistance. A facility's participation in the third party audit program proposed by this action would be totally voluntary. For facilities that choose not to participate in the program, this action would have no effect. However if a facility participates, this regulation would establish the requirements and regulatory incentives for their participation. For participating sources, the action would offer the potential for reduced regulatory burden (while maintaining their compliance responsibilities), flexible auditing options, and other benefits, provided the source meets the applicable requirements described in the rule. This action also would specify the proposed qualification requirements for persons desiring to act as third party auditors. EPA believes that this action would promote increased safety among facilities covered by the risk."*[89]

This proposal is clearly related to the third party audit option developed by the Wharton RMP Project team. One might speculate that the positive results of the Wharton Study group's evaluation of the effectiveness of third party audits of RMP facilities, contributed to EPA's development of its proposed third party audit regulatory option.

However, the proposed third party RMP audit option was withdrawn in 2003 for reasons not noted in the literature and never developed into a proposed Rule:

TABLE 3. CLEAN AIR ACT (CAA)--DISCONTINUED ENTRIES[90]

Regulation Identification Number	Title	Date	Comments
2050-A E85	SAN No. 4511 Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7); Third Party Audit Provisions	03/12/2003	Withdrawn: Agency Plans No Further Action

The authors are not aware of any further actions by EPA on this third party audit approach for improving implementation of the RMP Rule.

Given the character of the RMP Rule, (a "management-based regulation") and the fact that process accidents covered under the RMP Rule are low-probability events, it is of interest to examine how effective the RMP Rule has been in achieving its major objective: reducing reportable process accidents in RMP covered processes.

The RMP Rule requires covered facilities to report a process accident if it resulted in damages that exceeded specified loss consequences either on-site (within the facility) or off-site.[91]

In interpreting the effectiveness of the RMP Rule, one must keep in mind that:

1. The OSHA PSM regulation was directed at preventing process accidents capable of causing specified <u>on-site</u>, injuries to workers and contractors.

Whereas,

2. The major objective of the later EPA RMP Rule was directed at the prevention of process accidents capable of causing specified injuries and damages <u>off-site</u>, i.e., specified impacts to the public, off-site property or the environment.

A study of the incidence of RMP reportable accidents over time was done at the Wharton Risk Center under a cooperative agreement with EPA. The data used for these studies was obtained from the two five-year accident history reports that facilities covered under the RMP Rule were required to submit to EPA in June 1999 and June 2004.[92]

This study was completed in 2007 and some of the major findings of the study, briefly summarized on page 199 of the study, are as follows:

> *"RMP reported accident rates significantly declined between Waves 1 and 2 of RMP filings, both for all accidents and for accidents with reportable consequences. However, in contrast to this finding, we also found that there was <u>no decrease in the total accidents with reportable off-site</u> consequences, so that <u>the major reason for the decline was a decrease in on-site consequence accidents</u> <u>(emphasis added)</u>. The principal cause for this drop in accidents with on-site consequences is a decrease in the sub-category "injuries to employees and contractors" which are in essence OSHA reportable occupational illnesses and injuries (OII).*

What we can conclude from this discussion is that either the Rule, or the way the Rule has been administrated, has not met the expectations set forth in the original benefit/cost study of the Rule's benefits and costs.[93]

Observations on EPA's RMP Process Safety Standard

Most process safety practitioners believe, and investigations of reported process accidents in processes covered under the RMP Rule indicate, that if the provisions of the RMP regulation had been adequately implemented, almost all of the reported RMP covered process accidents might have been prevented: and there would have been a decrease in the total accidents with reportable off-site as well as on-site consequences.[94,95,96]

In early 2009, EPA's Inspector General Office (IG) pointed out significant weakness in regard to EPA's implementation of the RMP program and reported that:

> "EPA had not inspected or audited over half (296 of 493) of the high-risk facilities identified by EPA's Office of Emergency Management (OEM). Since most States have not accepted delegation of the program, EPA is responsible for ensuring compliance for over 84 percent of facilities nationwide. Of the 296 uninspected high-risk facilities managed by EPA, 151 could each impact 100,000 people or more in a worst-case accident. Accident data suggest uninspected high-risk facilities are more than five times as likely to have an accident than uninspected lower-risk facilities."[97]

In fact, long before the IG's 2009 report, some EPA managers apparently recognized that the resources EPA devoted to inspection and auditing of RMP facilities were inadequate and in 2001 they proposed the use of "voluntary" third party RMP audits to help address this resource problem.[98]

Unfortunately, as previously noted, this initiative, which would have partially addressed the shortcomings noted in the 2009 IG report, was withdrawn in 2003 for unknown reasons.

3. Role of USDA's Food Safety and Inspection Service (FSIS) in Ensuring the Safety of U.S. Meat Products

A. FSIS's functions and responsibilities

As noted in Appendix 1, more than 12 federal agencies regulate food safety in the United States. However, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture[99] has the major responsibility for ensuring the safety of meat, poultry, and egg products. The Food and Drug Administration (FDA) has this responsibility in non-meat related food areas.

The mission of FSIS is to ensure that meat slaughtering and processing operations produce safe products.[xiv] In order to accomplish this, FSIS requires that covered plant operations conform to the requirements of all of its standards.

[xiv] Every activity or product is associated with some probability of undesired consequences and therefore is not absolutely "safe." Presumably when a society adopts a regulation that deals with activities that have a potential for harm (are hazardous) it implicitly evaluates the likelihood of harm and judges that it is not at an unacceptable level.

"The FSIS meat inspection program is very comprehensive and includes among other things, requirements related to
1) Slaughtering operations[100]
2) Sanitation requirements for both meat slaughtering, and processing facilities [101]
3) Hazard Analysis and Critical Control Point (HACCP) requirements[102]

Current law stipulates that only federally inspected slaughter and processing operations can produce products that are destined to enter interstate commerce or be exported abroad. In order to receive Federal inspection, an establishment must apply for and receive an official "Grant of Inspection."

To receive federal inspection, an establishment must receive an official Grant of Inspection. To obtain this grant, an establishment must agree to abide by all FSIS regulations,[103] including the critically important Hazard Analysis and Critical Control Point (HACCP) regulation, which will subsequently be discussed in greater detail.

Having obtained a 'Grant of Inspection' allows slaughtering and meat processing facilities to operate provided a second requirement is met: FSIS inspection personnel must be present while the plant is operating. It is important to our subsequent discussions however, to recognize that the definition of FSIS "presence" depends on the nature of the meat operation:

- In regard to slaughtering facilities: "No animal may be slaughtered and dressed unless an inspector has examined it. One or more federal inspectors are on the line during all hours the plant is operating."
- In regard to processing: "Under current policies, processing plants visited once every day (emphasis added) by an FSIS inspector are considered to be under continuous inspection in keeping with the laws."

In the 2004-2005 periods, FSIS employed about 7,600 full-time residential inspectors in approximately 6,000 plants to discharge its meat safety program requirements.[104] Most of these employees' time was spent in monitoring slaughtering facilities.

It is also important to note that FSIS also conducts comprehensive Food Safety Assessments (FSA)[105] in addition to its routine monitoring of slaughtering and processing operations. An FSA focuses on evaluating how well a covered facility complies with FSIS requirements in regard to the design and validity of its HACCP plan, its Sanitation Standard Operating Procedures, its pre-requisite programs and its responses to food-safety control deviations.

Relatively recently[106] FSIS has committed to having Enforcement Investigation and Analysis Officers (EIAO) conduct routine FSAs in every plant, "at least every four years, and more frequently as needed."[xv]

[xv] It is interesting to compare the frequency at which FSIS seeks to verify covered facilities' compliance with major food safety requirements ("at least every four years"), with the requirement for annual verification that other agencies have in regard to public company financial statements, boiler and pressure vessel safety and vehicle safety inspections.

Covered meat plant's Implementation of all applicable FSIS Standards, and FSIS's confirmation that this has been accomplished appropriately, are not easy jobs. In particular, implementation of the HACCP regulation's requirements and FSIS's confirmation that this has been done appropriately require significantly more resources than is the case in regard to the Sanitation and other FSIS Standards.

Inevitably, some unsafe products will be produced and this gives rise to the second major challenge the meat industry faces: tracing the distribution of products identified as a potential source of consumer illness quickly in order to minimize consequent consumer illnesses.

Some brief comments on the "Traceability of Unsafe food Products" are given in Appendix 3 and the subject has been thoroughly discussed in a wide variety of papers produced by Economic Research Services[107] and others.[108, 109]

While improved traceability systems are important in reducing injuries resulting from the consumption of unsafe food products, reducing the production of such unsafe products through better industry compliance with the requirements of the FSIS HACCP regulation[110] probably has a greater potential for reducing such injuries than can be achieved by improvements in traceability.

B. FSIS's implementation of the HACCP regulation

Implementation of the FSIS HACCP regulation is probably the most important safety challenge that both FSIS and the meat processing industry currently face.

The USDA FSIS HACCP regulation is organized in eight sections:

417.1 Definitions
417.2 Hazard Analysis and HACCP Plan
417.3 Corrective actions
417.4 Validation, Verification, Reassessment
417.5 Records
417.6 Inadequate HACCP systems
417.7 Training
417.8 Agency Verification

Examination of the HACCP regulation's requirements shows that the regulation addresses the following seven principles that practitioners in both the private and government sectors believe any HACCP system must address:[111]

(1) Hazard analysis
(2) Critical control point identification
(3) Establishment of critical limits
(4) Monitoring procedures
(5) Corrective actions
(6) Record keeping
(7) Verification procedures

The FSIS HACCP Regulation, like the EPA RMP Regulation, is clearly a management-based regulation and does not "operationally define" the specific design, operation and inspection practices that must be in place in order for a covered process to be compliant with the HACCP regulation's requirements. Each covered facility must develop its own operational HACCP conformance plan based on its interpretation of the regulation, FSIS guidance, and the literature.

While the paper will not discuss the HACCP regulation's requirements in any depth, it will touch on two of its seven elements, "critical control point identification" and "establishment of critical limits" to illustrate the nature of this regulation.

Examination of these two elements of the regulation should give readers a better understanding of the HACCP regulation's character and requirements, the difficulties covered facilities face in implementing it "effectively," and the problems FSIS faces in verifying that effective implementation has been achieved.

The terms "critical control point" and "critical limit" are defined in the HACCP regulation as follows:

> Critical control point: "A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels."
>
> Critical limit: The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Dr. Ronald Jones of FSIS sums up the basis for these "critical limits" as follows:

> *"Critical limits can come from a variety of sources. They may be based on FSIS regulations or guidelines, FDA tolerances and action levels, scientific and technical literature, surveys, experimental studies or the recommendations of recognized experts (emphasis added) in the industry, academia, trade associations or processing authorities."*[112]

Dr. Jones also notes that:

> *"Each establishment must be able to provide a basis for their (emphasis added) decision regarding how they selected and developed their critical limits. This supporting documentation needs to be available for the inspector to review. A production process that has not met the critical limits may have produced an unsafe product."*

Since the HACCP regulation is a management-based' regulation, it does not offer full "operational guidance" on establishing critical limits or any of the other seven principles that are incorporated into this regulation.[113] This presents a difficult problem for covered facilities. For example, even if a covered facility has above average resources and makes an honest effort to achieve best practices, how does the facility identify all

"recognized experts" and then balance such experts' recommendations in arriving at what are acceptable "critical limits" for this specific facility's products?

Because of the management-based nature of the HACCP standard and the chronic shortage of FSIS resources, FSIS's implementation of its HACCP programs has not proceeded smoothly.

FSIS's implementation problems, and in particular its implementation of the HACCP regulation, have not gone unnoticed. For example, in 2002, ConAgra recalled 18 million pounds of E. coli contaminated ground hamburger and the USDA's Office of the Inspector General (OIG) report on this incident noted:

> "One of the factors led to the distribution of this defective product was that accurate assessments of HACCP plans had not been made because FSIS lacked sufficient competent staff to make those assessments" *(emphasis added).*[114]

In 2006, more than ten years after FSIS promulgated its HACCP regulation,[115] USDA's Office of the Inspector General (OIG) issued a report on the efficacy of FSIS assessments of covered facility's food safety and concluded:

> "Based on our audit results, we question whether FSIS has the systems in place, at this time, to provide reasonable assurance that risk can be timely or fully assessed, especially since FSIS lacks current, comprehensive assessments of establishments' food safety systems" *(emphasis added).*[116]

Both the 2007 CRS report[117] and 2009 CRS report [118] contained similar findings:

> "From time to time in the past, FSIS has had difficulty in sufficiently staffing its service obligations to the meat and poultry industries *(emphasis added).* Usually a combination of factors causes these shortages, including new technologies that increase plant production speeds and volume, insufficient appropriated funds *(emphasis added)* to hire additional inspectors at times of unexpected increases in demand for inspections, and problems in finding qualified people to work in dangerous or unpleasant environments or at remote locations. These staffing problems were complicated somewhat by the addition of HACCP requirements on top of the traditional inspection duties." *(emphasis added)*

These problems with FSIS's implementation of its HACCP regulation are not unique. They are generally true in regard to the implementation of almost all regulations that cover LP-HC Risks.

For example, as previously noted, in early 2009, EPA's Inspector General Office (IG) pointed out significant weakness in regard to EPA's implementation of its major accident risk management prevention (RMP) program.[119] The IG report noted that: "over 65 percent of all active RMP facilities had not received an on-site inspection or audit since inception of the Risk Management Program in 1999." It further noted that "Of the 296 uninspected high-risk facilities managed by EPA, 151 could each impact 100,000 people or more in a worst-case accident," and that "Accident data suggest uninspected

high-risk facilities are more than five times more likely to have an accident than uninspected lower-risk facilities."

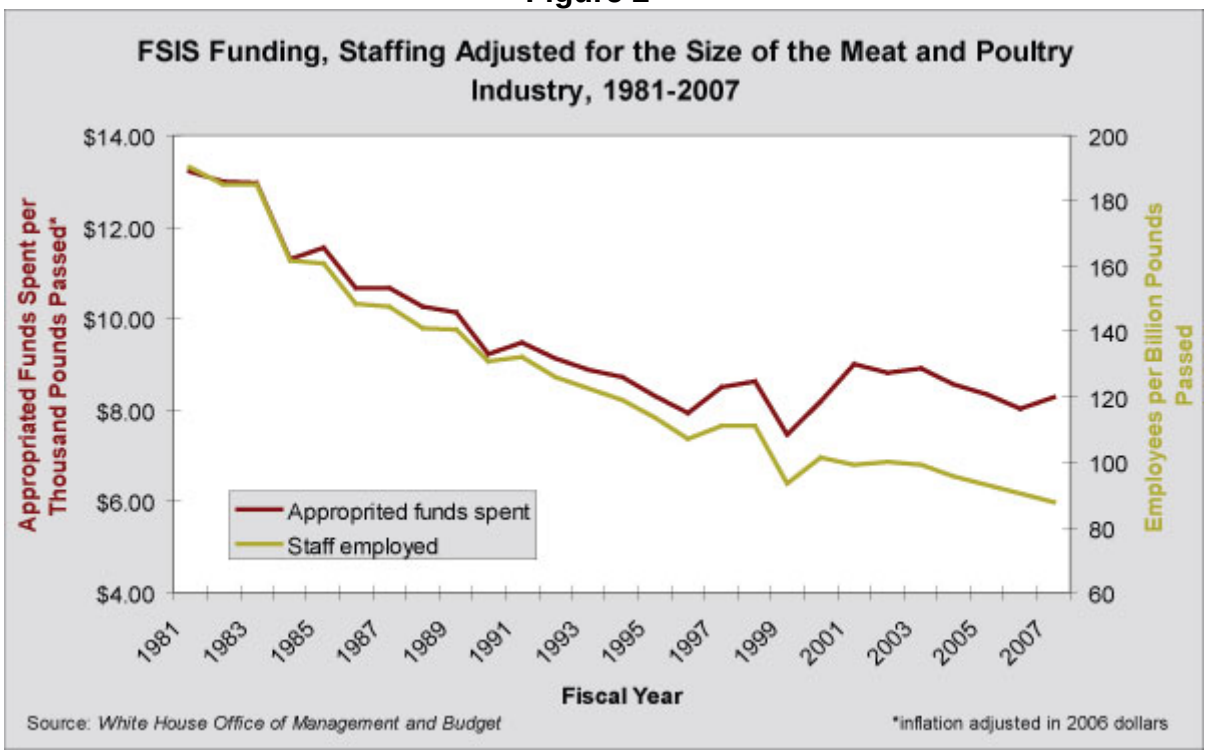
Similarly, OSHA's implementation of its major accident process safety management (PSM) program has been inadequate. As noted on page 200 of the U.S. Chemical Safety Board investigation of the catastrophic March 23, 2005, BP Texas City Refinery accident,[120] OSHA conducted only one planned PSM inspection of the Texas City refinery facility in the 1998–2005 time periods though this facility was one of the largest refineries in the United States. In contrast, the CSB notes on page 205 of its report that each of the nine refineries in the United Kingdom received detailed planned inspections annually by a multidisciplinary team.[121]

C. Problems affecting FSIS's implementation of its HACCP regulation

The previously noted findings of both the USDA's Inspector General and the Congressional Research Service (CRS) on the inadequacies of FSIS's HACCP oversight and auditing programs are not too surprising**,** since, as Figure 2 shows, FSIS staffing, adjusted for the size of the meat and poultry industry, has decreased over the last decade while its work load has been significantly increased by the need to:

- Assure the safety of a significantly larger volume of products.
- Provide the 'operational guidance' needed by both FSIS auditors and covered facilities to adequately discharge their respective responsibilities under the HACCP Regulation.

Figure 2[122]



The problem that FSIS faces in obtaining the resources needed to adequately assist and confirm covered facilities' compliance with its HACCP regulation is not unusual: It's a problem that most government agencies continually face in implementing regulations, and in particular, those dealing with Low Probability-High consequence (LP-HC) risks such as those addressed by the HACCP regulation.

4. Proposal on FSIS's use of Third Parties to improve its implementation of the HACCP Regulation

A. Introduction

As previously discussed FSIS faced, resource constraints, staffing difficulties and other problems that compromised its ability to adequately discharge its obligations for monitoring covered facilities' adherence to regulatory meat safety requirements.

Unfortunately, these problems continue and a December 2009 article in the *New York Times* noted:

> "Since January 2007, the industry has initiated 52 recalls of beef tainted with E. coli, compared with 20 in the three previous years. In one of the most recent cases, in October, a company in upstate New York recalled more than 500,000 pounds of ground beef after two people died and more than two dozen were sickened."[123]

This section of the paper focuses on the use of a third party audit program as a tool for assisting FSIS improve the discharge of its responsibilities for monitoring covered facilities compliance with its various meat safety regulatory requirements. It will outline the elements of a proposal calling for FSIS's use of third party auditors to monitor covered facilities implementation of the HACCP regulation.

The Third Party HACCP audit proposal incorporates "lessons learned" from the paper's previous examination of the role of third parties in assisting regulators implement four non-food related management regulations. Before presenting the Third Party HACCP Proposal, a synopsis of these "lessons learned" will be presented to assist readers in understanding the elements of the Third Party HACCP Proposal.

B. Synopsis of 'lessons learned' on third party roles in non-food regulations

This short synopsis will succinctly summarize, third party "lessons learned" from the previous examination of four non-food regulations that are relevant to FSIS's possible use of third party auditors in the implementation of its HACCP regulation.

These relevant lessons will be incorporated into the paper's subsequent proposal on use of third party audits in FSIS's HACCP oversight programs

State boiler and pressure vessels regulations

- Entities covered by the regulation: All facilities with operations that operate boiler or pressure vessels specified in the various state boiler and pressure vessel regulations.

- Regulatory objectives: Ensure the integrity and safe operation of boiler and pressure vessels.

- Regulatory requirements: By and large, the various state regulatory requirements are detailed by reference to the "operationally' framed" ASME Boiler and Pressure vessel code.[124]

- Verification of compliance: The various state regulatory agencies verify compliance annually through inspections conducted by either companies that insure covered parties against losses associated with boiler or pressure vessel accidents or regulatory agency employees.

- Funding for agency implementation of the regulation: The boiler regulations impose fees on regulated facilities to cover a significant portion of the regulatory agency's implementation costs.

- Effectiveness of regulation: The various state regulations achieved significant reductions in number of explosions associated with boiler and pressure vessel operations.

- Observations:
  i. A large majority of the inspections are conducted by either insurance company employees or third parties associated with insurance companies.
  ii. Compliance inspectors and third parties associated with insurance companies may not be completely unbiased, since insurance companies also experience losses from boiler accidents and benefit from facilities adhering to the boiler regulations requirements.

SEC requirements on the integrity of public company financial practices

- Entities covered by the regulation: All public companies.[xvi]

- Regulatory objective: The integrity of public company financial reports.

- Regulatory requirements: Public company compliance with:
  i. SEC financial reporting regulations[125]
  ii. Provisions of the Sarbanes-Oxley Act of 2002 (SOX)

[xvi] Public company: a company whose shares can be bought and sold on the stock market. These companies must comply with stringent reporting requirements set out by the Securities and Exchange Commission, including the public disclosure of financial statements.

- Agency verification of compliance:
  i. SEC reviews of annual public firms' 10-K and related forms.
  ii. Public Company Accounting Oversight Board (PCAOB) audits.

- Funding for Agency implementation of the regulation:
  i. Funds appropriated by Congress for SEC operations.
  ii. Fees imposed by PCAOB on companies covered under SOX.

- Effectiveness of SOX: Presently insufficient data for making sound judgment.

- Observations:
  i. CPAs collected fees from public companies for verifying their compliance with SEC requirements on the integrity of financial practices. Prior to SOX, the objectivity of such reports was often compromised because the CPA performing the audit, or firms that employed them, also derived substantial revenues for other services from the firms they audited for compliance with SEC requirements on financial integrity. Presumably, PCAOB's surveillance efforts and new responsibilities placed on various officers of public companies will alleviate the extent of the deviations from sound accounting practices that occurred prior to the enactment of SOX.

1988 amendments to OSHA mechanical power press standard[126]

- Entities covered by the amendments:
  i. All facilities with mechanical power press operations that employ presence sensing device initiation (PSDI).

- Regulatory objective:
  i. Safer use of presence sensing device initiation of mechanical power presses.

- Regulatory requirements:
  i. Employer must certify that the PSDI installation meets requirements (a) through (h) of the regulation.

- Agency verification of compliance:
  i. OSHA qualified third party used to validate covered facilities' certification that its PSDI power presses met requirements of 29 CFR 1910.217 (a) through (h).

- Funding for agency implementation of the regulation:
  i. The funding of OSHA third party validators was not clearly spelled out in the regulation.

- Effectiveness of regulation:
i. Regulation never implemented.

- Observations:
  i. This regulation was never implemented because no qualified third parties responded to OSHA's request for candidates for the validator function.
  ii. The literature indicates that the reason for this was that no candidate third party validator believed that it was possible to attest to Regulation's requirement that: "no single failure or single operating error will cause injury to personnel from a point-of-operation hazard" even if they had determined that a power press met all of the Regulations safety requirements.
  They believed, that taken literally, no mechanical power press could meet this Regulatory requirement and were concerned about the risk of incurring liability if they validated a mechanical power press installation and subsequently a very low probability accident occurred causing injuries somehow related to operation of a PSDI press that they had validated.

EPA's Process Safety Standard (RMP Rule)[127]

- Entities covered by the amendments:
  i. Facilities that manufacture, use, store, or otherwise handles more than a threshold quantity of a listed regulated substance in a process.

- Regulatory objective:
  i. Reduction of covered chemical process accidents impacts on the public.

- Regulatory requirements:
  i. Hazard assessment that details the potential effects of an accidental release, an accident history of the last five years, and an evaluation of worst-case and alternative accidental releases scenarios.
  ii. Prevention program that includes safety precautions and also maintenance, monitoring, and employee training measures.
  iii. Emergency response program that spells out emergency health care, employee training measures and procedures for informing the public and response agencies (e.g., the fire department) should an accident occur.

- Verification of compliance:
  i. The RMP Rule requires covered facilities to certify their compliance with the Rule every three years. However it does not require that EPA carryout physical audits of covered facilities' compliance with the Rule.

- Funding for agency implementation of the regulation:
  i. Congressional appropriations for EPA.

- Effectiveness of regulation:
  i. EPA's Office of Inspector General concluded that, "EPA's inspection process is not strong enough to provide assurance that facilities are complying with program requirements."[128]

- Observations:
  i. Shortly after the RMP Regulation was issued, EPA appears to have recognized that its oversight of RMP facilities compliance needed strengthening. In April 2001, Belke, an employee of EPA's Chemical Emergency Preparedness and Prevention office (CEPPO) which managed implementation of the RMP regulation, presented a paper that discussed EPA's RMP implementation program, and noted:

     "Considering the difficulty inherent in risk management program audits, and the small number of government inspectors available (emphasis added) to do them, it is unlikely that EPA will ever be able to regularly perform comprehensive RMP audits on more than a small fraction of the total number of regulated facilities. Recognizing these realities, EPA is considering the feasibility of a voluntary program where qualified third parties[xvii] (emphasis added) would perform comprehensive RMP audits at facilities that volunteer to undergo such an audit."[129]

In December 2001, EPA proposed a regulation aimed at the addressing this resource problem. The proposal called for covered facilities to conduct voluntary third party audits of facility RMP compliance programs.[130] In 2003, this proposal was withdrawn for unstated reasons[131] and this may have contributed to the EPA's Inspector General Office finding in 2009 that EPA's RMP audit program was inadequate.

C. Justification for the increased use of third party audits funded by fees in order to improve FSIS implementation of the HACCP regulation

As the non-profit Center for Science in the Public Interest confirms, FSIS's inspection programs are critically underfunded:

"FSIS's inspector vacancy rates of 10% to 20% pose a major challenge to adequately inspecting meat and poultry plants. In 2007, FSIS employed only 88 workers per billion pounds of meat, a 54% drop since 1981. That inevitably leads to more recalls and other program failures, such as occurred with the Westland/Hallmark plant that recalled million pounds of meat because of violations of humane treatment laws. More funding for more inspectors is critical to protecting the public health" (emphasis added).

The noted chronic underfunding faced by FSIS in regard to ensuring food safety is not unique: FDA's food safety programs are generally acknowledged as being even more grossly underfunded than USDA/FSIS food safety efforts. In an effort to at least partially address its funding problems, FDA proposed a Food Protection Plan in 2007 that dealt with a wide range of issues including the legislative authority needed to authorize FDA to implement a voluntary food inspection program executed by qualified third parties (See Appendix 4).

[xvii] In this context, a third party is someone not employed by either an RMP implementing agency or an RMP-regulated facility."

USDA's National Organic Program[132] also employs "Certifying Agents" who are in essence USDA approved third party auditors paid by the facility to verify their compliance with the regulations requirements.

As noted previously, there are also numerous other regulations that employ third party auditors supported by fees imposed on covered facilities to verify their compliance with the regulations requirements.

The next section of the paper will outline a proposal on the use of third party auditors, aimed at alleviating the problems FSIS faces in adequately ensuring that covered facilities adequately implement its critically important HACCP regulation. This proposal will incorporate lessons learned from the paper's examination of four non-food regulations and the literature.

D. Outline of a proposed third party HACCP audit program

Section 1: Objective of the proposed third party audit program: Ensure that FSIS has the capacity to adequately audit covered facilities compliance with HACCP regulatory requirements and in particular, the requirements of section § 417.8 of the HACCP regulation which reads as follows:

> § 417.8 Agency verification: FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:
> (a) Reviewing the HACCP plan;
> (b) Reviewing the Critical Control Point (CCP) records,[xviii]
> (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
> (d) Reviewing the critical limits;
> (e) Reviewing other records pertaining to the HACCP plan or system;
> (f) Direct observation or measurement at a CCP;
> (g)Sample collection and analysis to determine the product meets all safety standards; and
> (h) On-site observations and record review.

Section 2: Required qualifications for third party auditors: FSIS third party auditors shall have the following qualifications:

a. Educational background, knowledge and experience equivalent to that which FSIS would require of members of its staff detailed to execute specified audit functions.[133]
b. Commitment to be available for at least a specified number of FSIS audit assignments each year.
c. Agreement to treat the results of audits they perform for FSIS as confidential government information unless FSIS explicitly releases them from this obligation in regard to a specific audit.

[xviii] Critical Control Point (CCP). "A point, step, or procedure in a food process at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels".

d. Ability to establish either:
    i. Their neutrality and independence,
  Or
    ii. That they have satisfactorily conducted HACCP audits on behalf of insurance companies that provided coverage to meat and poultry processing firms for losses resulting from customer injury or required product recalls.

Section 3: FSIS's responsibilities in accepting and acting on third party auditor findings:

a. Verifying that the third party audit report cover assessment of all § 417.8 Agency verification requirements.
b. Judging whether the third party audit findings justify issuing non-compliance citations.[134]
c. Issuing a final facility audit report.
d. Conducting an FSIS re-inspection to evaluate the validity of a "non compliance" finding, if the finding is disputed by the audited facility.

Section 4: Funding of third party audits:

a. FSIS will assess covered facilities for all or part of the cost of such third party audits, i.e., impose audit fees

E. Discussion of the FSIS HACCP third party audit proposal

There are two items in the FSIS HACCP third party audit proposal that particularly warrant further discussion. The first item (Item 1) deals with the funding of FSIS third party audits and the second item, (Item 2) deals with the option of using individuals who are, or have been associated with insurance companies as third party auditors

Item 1: Funding of FSIS third party audits

The proposal calls for FSIS to impose fees on covered facilities to cover the cost of third party HACCP audits.

Perusal of the literature indicates that this element of the proposed program will be difficult to implement because many industry and consumer groups oppose funding of FSIS's routine meat inspection programs with imposed fees. This has led Congress to consistently reject FSIS requests for the authority to charge user fees for more of its operations[135] despite the widely accepted belief that Congressional funding of FSIS food safety programs has not been adequate.

A specific example of industry opposition to the imposition of fees to fund FSIS routine inspection programs is found in the Congressional testimony of J. Patrick Boyle, President of the American Meat Institute. Boyle testified that:

> "A final concern as it relates to food safety is the imposition of a user fee that would be paid by the regulated industry for food inspection services. Similar proposals for meat and poultry inspection at USDA have been rejected by Congress annually for

nearly 30 years. USADA inspection services have long been paid for with government funds because those inspections are activities that benefit the general public. Inspection activities should be funded not from user or registration fees that, in effect, are a food tax, by from monies appropriated out of the general treasury."[136]

Some consumer groups also oppose funding of FSIS food inspections by imposed fees on covered facilities. Carol Tucker-Foreman representing Consumer Federation of America in her testimony to congress noted that:

> "The FSIS budget includes, again, a stated intention to ask Congress to approve user fee legislation to cover increasing program costs. USDA uses this device to project a savings of $96 million in FY 2009. It is irksome to us, and I presume to you, that USDA trots this proposal out regularly to cover its failure to request enough funding to cover meat and poultry inspection programs. Congress has rejected this proposal many times. Over the past 35 years consumer groups have consistently opposed user fees. On this issue, as with increasing funding for FDA, we have agreed with associations representing the food industry" (emphasis added).[137]

Unfortunately, there are very few indications that industry or consumer groups are likely to change their positions on using imposed fees to fund third party auditors despite the previously discussed ongoing inability of FSIS to fully staff its inspection programs with its current Congressional funding.

However, the advent of a major unsafe food incident associated with the failure of FSIS to adequately audit a facility because of funding problems might arouse public outrage and alter consumer groups' opposition to imposed inspection fees in order to ensure that similar failures do not occur as a result of inadequate FSIS funding.

***Item 2: Use of third party auditors associated with insurance companies*.**
Traditionally, third parties' independence, like that of Caesar' wife "should be above reproach." Unfortunately, in the real world this is unlikely. (See "*The integrity of financial reports on public companies*" in Section 2-B of this paper.)

As the Enron case showed, many supposedly independent Certified Public Accountants that certified public company financial statements, as required under the provisions of SEC regulations, or the firms that employ them, often solicited other types of business from the same companies and this compromised their required independence.

Similar situations occur in the food industry as shown in a recent *New York Times* article on the Peanut Corporation of America's product contamination accident.[138]

Given the difficulty of ensuring an adequate supply of completely unbiased third party auditors capable of assessing industry conformance with FSIS's HACCP regulatory requirements, leads the authors to suggest that the third party audit proposal should allow for a "second best" alternative: auditors whose self interest or bias, if any exists, is likely to tends towards interpreting required compliance measures that in a manner that

is are stronger than what is legally required by the provisions of FSIS HACCP regulation: employees associated with insurance companies that provide food processing firms with product liability, or recall insurance are an example of this second best alternative to the completely unbiased auditor.

However, the paper's third party proposal recognizes that a third party auditor's noncompliance finding may impose financial and emotional costs on the audited food processing firm, even if the finding is later overturned following a challenge by the cited facility. For this reason, as previously noted, to reduce the likelihood of an unjustified third party noncompliance finding, the proposal calls for a review of all third party noncompliance findings by FSIS staff before a non-compliance finding is officially accepted.

The decision to choose this second best alternative is justified because the food risks addressed by FSIS are risks imposed on the public which the public cannot either completely avoid or discern a priori. Furthermore, even if a food processing company is unfairly cited for non-compliance, there are well established regulatory procedures that allow the company to have any non-compliance citation withdrawn if they can demonstrate that indeed the findings are unfounded.

Though a food processing firm may unfortunately suffer losses even if a non-compliance finding is later deemed to be unfounded, such losses do not compare with the losses (deaths and injuries) that members of the public may experience as a result of a food firm's under-compliance with the provisions of the FSIS HACCP regulation.

Moreover, while the food processing firm can take steps to eliminate the distribution of almost all disease contaminated products, the consumer cannot discern a priori whether a food product is unsafe. Fortin describes this problem succinctly as follows:[139]

> *"It is well documented that the market provides incomplete information on a product's risk of inducing foodborne illness.[140] Consumer information on unsafe food is incomplete both before and after purchase. Unlike food spoilage organisms, foodborne pathogens often are invisible, odorless, and tasteless. Consumers cannot examine their food and determine that it is free from pathogens. Further, the vast majority of foodborne illness is never traced back to its cause. This market inefficiency creates an underproduction of food safety that a fully functional and competitive market would produce.[141]*
>
> *For the market system to work, consumers would need inexpensive access to complete information on the safety of their food either before or after purchase. Unfortunately, even the limited available information generally is very costly to obtain as foodborne pathogen determination requires expensive investigation and laboratory testing.[142] Even if an ill consumer did somehow complete such investigation and laboratory testing, he or she would have no way to communicate the information among the large number of people needed to conduct the epidemiology for a foodborne illness investigation.[143]*
>
> *Moreover, information on foodborne illness generally is not available at any cost.*
>
> *Rarely is the cause of a foodborne illness traced back to the causative food. More than eighty percent of foodborne illness may be unreported; and, even when reported, causation is difficult to prove."*[144]

The proposed FSIS use of third party auditors associated with insurance companies is not a new concept. Prior discussions in this paper and a series of studies by the Wharton Risk Center[145] show that the use of third parties associated with insurance companies has been an effective tool in implementing a number of regulations in addition to the facility boiler and pressure vessel regulations. For example, one of these Wharton studies showed that:

> "Eliminating a state-level government assurance program and switching to private insurance markets to finance cleanups reduced the frequency of costly underground fuel storage tanks leaks by more than 20 percent. This corresponds to more than 3,000 avoided fuel-tank release accidents over eight years in one state alone, a benefit in avoided cleanup costs and environmental harm exceeding $400 million."[146]

Cunningham[147] has also proposed using what is in essence insurance company sponsored third party audits of company financial statements and Skees,[148] Havinga,[149] and Henson[150] have each discussed aspects of this proposition in regard to improving to food safety.

F. Closing Observations

FSIS's inability to obtain the resources needed to adequately confirm covered facilities' compliance with its HACCP and other food safety regulations is not unusual. It is a chronic problem: most government agencies cannot obtain the resources needed to adequately implement their regulations, particularly those dealing with Low Probability-High Consequence (LP-HC) risks such as those addressed by the HACCP regulation.

However, confirming compliance with the HACCP regulation is a particularly difficult task, since this regulation is a management-based regulation and does not "operationally define" the specific practices that must be in place in order for a covered process to be compliant with the HACCP regulation's requirements. Each covered facility develops its own operational HACCP conformance plan based on its interpretation of the regulation, FSIS guidance, and the literature.

FSIS does review the operational adequacy of covered facilities practices for implementing the HACCP regulation in the course of its comprehensive Food Safety Assessments (FSA). However, even today a facility FSA may be done as infrequently as once in four years, again due to FSIS's inadequate resources.

Given the health and financial consequences of FSIS inadequate implementation of its HACCP and related food safety requirements due to the previously noted lack of adequate funding, the paper's proposal that FSIS be authorized to impose fees on covered facilities that would allow it to employ third party auditors to address this problem seems to be ethically and financially justified.

Unfortunately, as previously discussed, implementation of any FSIS scheduled meat inspection program funded by imposed fees will face opposition from some food industry and consumer organizations since they object to the use of imposed fees to fund any FSIS scheduled meat inspection program. The authors believe that consumer group opposition to funding a regulatory food safety measure with imposed fees is somewhat idiosyncratic, given the lack of equivalent opposition to the funding of other regulation's mandated third party audits, such as those dealing with public company financial statements, boiler and pressure vessel safety and vehicle safety inspections.

Examination of the logic and underlying reasons for some consumer group's opposition to the funding of scheduled FSIS meat inspection programs could be the subject of an interesting research study.

Appendix 1[xix]

Department and/or agency		Responsible for
U.S. Department of Agriculture	Food Safety and Inspection Service	All domestic and imported meat, poultry, and processed egg products
	Animal and Plant Health Inspection Service	Protecting the health and value of U.S. agricultural resources (e.g., animals and plants)
	Grain Inspection, Packers and Stockyards Administration	Establishing quality standards, inspection procedures, and marketing of grain and other related products
	Agricultural Marketing Service (AMS)[a]	Establishing quality and condition standards for dairy, fruit, vegetable, livestock, meat, poultry, and egg products
	Agricultural Research Service	Conducting food safety research
	Economic Research Service	Providing analyses of the economic issues affecting the safety of the U.S. food supply
	National Agricultural Statistics Service	Providing statistical data, including agricultural chemical usage data, related to the safety of the food supply
	Cooperative State Research, Education and Extension Service	Supporting food safety research, education, and extension programs in the land-grant university system and other partner organizations
Department of Health and Human Services	Food and Drug Administration (FDA)	All domestic and imported food products except meat, poultry, or processed egg products
	Centers for Disease Control and Prevention (CDC)	Protecting the nation's public health, including foodborne illness surveillance
Department of Commerce	National Marine Fisheries Service	Voluntary, fee-for-service examinations of seafood for safety and quality
Environmental Protection Agency		Regulating the use of pesticides and maximum allowable residue levels on food commodities and animal feed
Department of the Treasury	Alcohol and Tobacco Tax and Trade Bureau	Enforcing laws covering the production, use, and distribution of alcoholic beverages
Department of Homeland Security [b]		Coordinating agencies' food security activities
Federal Trade Commission		Prohibiting false advertisements for food

Source: GAO.

[a] According to USDA, AMS has no statutory authority in the area of food safety. However, the agency performs some functions related to food safety for several foods. For example, AMS graders monitor a shell egg surveillance program that identifies cracked and dirty eggs. In addition, AMS performs functions related to food safety for the National School Lunch Program.

[b] In 2001, by executive order, the President stated that the then Office of Homeland Security, as part of its efforts to protect critical infrastructures, should coordinate efforts to protect livestock, agriculture, and food systems from terrorist attacks. In 2002, Congress enacted the Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002), setting out the department's responsibility to protect and secure critical infrastructures and transferring several food safety-related responsibilities to the Department of Homeland Security. As a result of the executive order, the Homeland Security Act of 2002 establishing the Department of Homeland Security, and subsequent presidential directives, the Department of Homeland Security provides overall coordination on the protection of the U.S. food supply from deliberate contamination.

[xix] "FOOD SAFETY Experiences of Seven Countries in Consolidating Their Food Safety Systems", GAO05-212, February 2005, http://www.gao.gov/new.items/d05212.pdf

Appendix 2

Definitions of the Roles of "First", "Second" and "Third" Parties and Related terms

1. Source: National Conformity Assessment Principles For The United States[151]

Accreditation
Third party attestation related to a conformity assessment body conveying a formal demonstration of its competence to carry out specific conformity assessment tasks. (These tasks include sampling and testing, inspection, certification and registration.)

Certification
Third party attestation related to products, processes, or persons that convey assurance that specified requirements have been demonstrated.

Conformity Assessment
Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (This may include any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.)

First, Second and Third Party
The first party is generally the person or organization that provides the object, such as the supplier. The second party is usually a person or organization that has a user interest in the product, such as the customer. The third party is a person or body that is recognized as being independent of the person or organization that provides the object, as well as the user or customer of the object.

Inspection[xx]
Examination of a product design, product, process or installation, and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements.

Recognition
Procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include accreditation of testing laboratories and inspection, certification and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

Registration
Third party attestation related to systems that convey assurance that specified requirements have been demonstrated. Such systems include those established for the management of product, process or service quality and environmental performance.

[xx] In the authors' opinion, as used the term "inspection" is synonymous with "audit."

2. Source: ANSI-ASQ National Accreditation Board (ANAB)*

"First, Second and Third Party Approach: Organizations develop and implement management systems to combat and control variation. The management system details definition, implementation, control and audit, corrective and preventive action, improvement, and redesign.

Documenting a management system—by developing written work procedures, forms, and records—can help ensure that the organization operates in a structured way to maximize efficient use of time and resources. Systemizing how things are done ensures that nothing important is overlooked and responsibilities are clear to everyone," according to the International Organization for Standardization (ISO).

As ISO notes, management system standards provide a good model for organizations to follow. A management system that conforms to an international standard is built on what ISO calls "a firm foundation of state-of-the-art practices arrived at by the consensus of experts in the field."

To be effective, a management system must be complied with consistently. To ensure consistent compliance of their management systems, organizations can pursue a number of alternatives.

A business may use its own internal auditors to ensure ongoing compliance—what can be referred to as a "first-party" method. Ensuring compliance is entirely driven by the organization itself (the "first party"), and its auditors are typically trained with little or no outside help.

When an organization is contractually obligated to make sure it meets specific customer requirements, a "second-party" method of ensuring compliance may be used. While implementation and control of the management system remains the responsibility of the business, which may still conduct internal audits, the organization's customers (the "second party") reserve the right to conduct their own audits, and may also participate in corrective and preventive action and improvement action and redesign.

In the "third-party" approach, the business bases its management system on an international standard and has the system audited by an independent certification body (the "third party"). Organizations that engage in the third-party process are required to conduct internal audits. Their internal auditors are trained on (and perhaps certified to) the requirements of the international standard. While some customers may still conduct second-party audits, certification has the potential to eliminate multiple audits of the management system—and thus the time and resources required to conduct them—because all parties can rely on the verification of compliance provided by the third-party certification body.

Reference: ANAB letter to DNV: Taken from 'ISO Facts Volume 7 Issue 3, April, 2007
http://www.dnvcert.com/DNV/Certification1/News/NewsLetter/ISOFactxVolume7Issue3/

3. Source: The Ethical Trading Initiative (ETI)*

"Third party (audit, assessment, inspection, monitoring, verification etc): An audit or inspection carried out by a party other than the supplier (first party) or the sourcing company** (second party)."

The term "third party audit" (or inspection, assessment etc) can be misleading because it implies an independence that may not exist. In actual practice third party audits are usually conducted by organizations in some form of agency relationship with one of the parties. A third party audit would be independent only where the person paying for the audit is not able to influence the results by virtue of the fact that they are paying for the audit. This would also imply the existence of rules governing the audit process that were widely accepted as unbiased and robust.

*The Ethical Trading Initiative (ETI) is an alliance of companies, nongovernmental organizations (NGOs) and trade union organizations

**Sourcing company: A company that purchases product from another company for either direct or indirect onward sale to the consumer.

Reference: http://www.ethicaltrade.org/Z/ethtrd/gloss/index.shtml

4. Source: English Dictionary- With Multi-Lingual Search, Allwords .com

"Third party: Someone not directly involved in a transaction. A third entity in the Seller (first party) and Customer (second party) relationship. A Seller may employ a third party to perform specific services to augment the value of a product. For example, a manufacturer may employ a third party to pack and distribute a product. A computer manufacturer may augment their product with software from a third party supplier"

Reference: Dictionary- With Multi-Lingual Search, Allwords.com http://www.allwords.com/word-third+party.html

5. Source: ASTM

"Another key to understanding conformity assessment system design is characterizing the involved parties by their relationship to commerce. For this we use simple definitions of the involved parties.

- First party – The manufacturer and/or supplier.
- Second party – The purchaser and/or user.
- Third party – An independent party that has no interest in the transaction between the first and second party.

Government has a unique role in regulation that does not fit neatly into these definitions, but is the second party in procurement.

Third-Party Conformity Assessment: Third-party conformity assessment is often utilized in situations where the need for confidence is higher than a first- or second-party conformity assessment system can provide and where other factors do not reduce the needed rigor and independence. This provides a higher level of confidence in compliance to purchasers and users since the third party's decision-making process is free from any influence of the business between the first and second parties. Third parties can be laboratories on whose test data determinations of compliance are based: inspection bodies, certification bodies and/or registration bodies."

Reference: ASTM Standardization News: "Making the Confidence Connection: Conformity Assessment System Design" by Gordon Gillerman http://www.astm.org/SNEWS/DECEMBER_2004/gillerman_dec04.html

6. Source: United Nations

"Certification is a procedure by which a third party gives written assurance that a product, process or service is in conformity with certain standards.[152] Certification can be seen as a form of communication along the supply chain. The certificate demonstrates to the buyer that the supplier complies with certain standards, which might be more convincing than if the supplier itself provided the assurance.

The organization performing the certification is called a certification body or certifier. The certification body might do the actual inspection, or contract the inspection out to an inspector or inspection body. The certification decision, i.e. the granting of the written assurance or "certificate" is based on the inspection report, possibly complemented by other information sources.

Certification is always done by a third party. The verification is done and the assurance is provided by a party without direct interest in the economic relationship between the supplier and buyer. An internal control is a first-party verification. When a buyer verifies if the supplier adheres to a standard, it is a second-party verification.

It is important to note that third-party verification does not automatically guarantee impartiality or absence of conflicts of interest. First, the standard-setting can be done by any party. The producer (first party) can set the standard, in which case the producers' interests are likely to be reflected in the standard. Also the buyer (second party) can set the standard, in which case business interests will be reflected in the standard. Second, if the standard-setting and certification body are one and the same body, this can also cause conflicts of interest. The standard-setting body would like to see high implementation rates of its standard, or have a bias against certain types of producers for ideological reasons, which can influence certification decisions. Third, a conflict of interest might arise depending on who pays for the certification costs. Commercial certification

Reference: "Environmental and social standards, certification and labeling for cash crops", by Dankers, C. and Liu, P, Food and Agriculture Organization of the United Nations, Rome, 2003"

7. Source: ISO 9000:2000

"3.9 Terms relating to audit
NOTE: The terms and definitions given in 3.9 have been prepared in anticipation of the publication of ISO 19011. It is possible that they will be modified in that standard.
3.9.1 Audit: Systematic, independent and documented process (3.4.1) for obtaining audit evidence (3.9.4) and evaluating it objectively to determine the extent to which audit criteria (3.9.3) are fulfilled

NOTE: Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization (3.3.1) itself for internal purposes and can form the basis for an organization's self-declaration of conformity (3.6.1).

External audits include what are generally termed "second-"or "third-party audits".

Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external independent organizations. Such organizations provide certification or registration of conformity with requirements such as those of ISO 9001 and ISO14001:1996."

Reference: ISO 9000:2000: Quality management systems – Fundamentals and vocabulary, ICS 03.120.10, ISBN 0-86928-841-5, BSI. British Standards Institution

8. Source: ISO Committee on Conformity Assessment

"The process of determining whether products, processes, systems or people meet specified requirements has been given the name, conformity assessment. ISO's Committee on Conformity Assessment (CASCO) provides several ISO guides on the subject. The tools of conformity assessment are listed in the order of their emergence in Table 3 with an asterisk to indicate usage by first parties (suppliers), second parties (customers, regulators, or others who demand compliance with requirements) and third parties (body's independent from both suppliers and their customers)."

Table 3: The "tools" of conformity assessment and who uses them.

	First Party	Second Party	Third Party
Manufacturer's declaration	*		
Inspection	*	*	*
Testing	*	*	*
Auditing	*	*	*
Certification			*

Manufacturer's declaration of conformity:

Commonly called self-certification it is, according to the definition under ISO/IEC Guide 2, what a supplier (first party) does in giving written assurance that its product meets specified requirements (e.g. a standard specification for the product). It is the earliest and most common form of conformity assessment and may be supplemented by the other forms of conformity assessment: typically inspection and/or testing (including calibration) of the product, auditing of related product production systems and processes, and more recently, certification (or registration) of the supplier's quality system. ISO/IEC Guide 22 covers manufacturer's declaration of conformity principles.

Reference: Agilent Technologies: http://metrologyforum.tm.agilent.com/conform.shtml

9. Source: Quality Engineered Systems (QES)

First Party Audits: Conventionally, a first party audit is conducted on your organization's own management system and internal structures by your organizations' own audit resource and is therefore under your direct control. You are implementing or maintaining your quality management system and will therefore want to conduct self-assessments or first party audits to test compliance of your own systems. To improve your confidence in your own audit team during implementation, you will engage QES to assist and guide you through the pitfalls of the first steps in conducting your own audits.

Second Party Audits: Any organization concerned about quality will want to be certain of their suppliers and can gain this confidence through conducting audits of their supplier's management systems and their ability to meet contract requirements. Most small businesses, with staff already performing additional "quality management" support functions as well as their normal duties, do not have the capacity to conduct these audits. QES has the capacity and the expertise to conduct these audits on your behalf. The use of an uninvolved party such as QES also creates a perception of fairness and objectivity in the eyes of the Supplier.

Third Party Audits: It is generally accepted that a third party audit is conducted by a certification body to verify and validate your management system. As a precaution, you may seek another unbiased outside assessment prior to the certification body assessment. This is done to address any oversights of your own first party audits. QES has added value to many an organization's management system through this final intervention, ensuring a 100% success rate at certification.

Reference: Quality Engineered Systems (QES), 2007 http://www.qesystems.co.za/auditing.htm

10. Source: The ANSI-ASQ National Accreditation Board (ANAB)

Certification of first, second and third party(s)

1. The ANSI-ASQ National Accreditation Board (ANAB) is the U.S. accreditation body for management systems. ANAB accredits certification bodies (CBs) for:

- ISO 9001 quality management systems (QMS)
- ISO 14001 environmental management systems (EMS)
- ISO 22000 food safety management systems (FSMS)
- ISO 28000 supply chain security management systems (SCSMS)
- ISO/IEC 20000-1 information technology service management systems (ISMS)
- ISO/IEC 27001 information security management systems (ISMS)
- ANSI/AIHA Z10 occupational health and safety management systems (OHSMS)
- Numerous industry-specific requirements

ANAB is a member of the International Accreditation Forum and a signatory of the IAF multilateral cooperative arrangements (MLAs) for QMS and EMS. Through the IAF MLAs and the Multilateral Cooperative Accreditation Arrangement, ANAB cooperates with other accreditation bodies around the world to provide value to its accredited CBs and their clients, ensuring that accredited certificates are recognized nationally and internationally. The global conformity assessment system ensures confidence and reduces risk for customers engaging in trade worldwide.

Reference: ANSI-ASQ National Accreditation Board

11. Source: Legal Explanations

Various Definitions of Third Party: It is worth noting however that Third Party: It is someone other than the first two principals who have entered into a contract or an agreement. A third party is not a direct party in the agreement or contract, but they may be present as a beneficiary to the contract or someone affected by the contract between the first two principals (first party and second party). This could be the case of third party insurance in automobile industry where if one of the principals is insurance company and another is the automobile owner. The automobile owner if, damages the third party's (someone else's) car by an accident, and has a third party insurance cover, the insurance company covers up for the damage for the third party's car. Reference:

Reference: Legal-Explanations.com Homehttp://www.legalexplanations.com/definitions/third-party.htm

12. Source: Free Dictionary

The Florida statute governing the Medicaid program defined “third party” as:
“Third party. n. a person who is not a party to a contract or a transaction, but has an involvement (such as a buyer from one of the parties, was present when the agreement was signed, or made an offer that was rejected). The third party normally has no legal rights in the matter, unless the contract was made for the third party's benefit.”

Reference: http://www.thefreedictionary.com/Third+Party

13. Source: Business Dictionary

Third Party: Someone who may be indirectly involved but is not a principal party to an arrangement, contract, deal, lawsuit, or transaction

Reference: http://www.businessdictionary.com/definition/third-party.html

14. Source: The Complete Guide to the CQA by Stephen Baysinger

First Party, Second Party and Third Party Audits
FIRST PARTY (INTERNAL) AUDIT: A first party audit is usually performed by the company (or a department within the company) upon itself. It is *an audit of those portions of an organization’s quality assurance program that are "retained under its direct control and within its organizational structure."* (ANSI/ASQC NQA-1 (1986)) A first party audit is usually conducted by the organization’s internal audit group. However, employees within the department itself may also conduct an assessment similar to a first party audit. In such an instance, this "audit" is generally referred to as a "self assessment."

The purpose of a self assessment is to monitor and analyze key intra-departmental processes which, if left unattended, have the potential to degenerate and negatively affect product quality, safety and overall system integrity. These monitoring and analyzing responsibilities lie directly with those most affected by departmental processes—the employees assigned to the respective departments under examination.

Although first party audit/self assessment ratings are subjective in nature, the ratings guideline shown here helps to hone overall rating precision. If performed properly, first party audits and self assessments:

- Provide feedback to management that the quality system is both implemented and effective, and;
- Are excellent tools for gauging an organization's continuous improvement effort as well as measuring the return on investment for sustaining that effort.

SECOND PARTY (EXTERNAL) AUDIT

Unlike the first party audit, a second party audit is *an audit of another organization's quality program not under the direct control or within the organizational structure of the auditing organization. (ANSI/ASQC NQA-1 (1986))* Second party audits are usually performed by the customer upon its suppliers (or potential suppliers) to ascertain whether or not the supplier can meet existing or proposed contractual requirements. Obviously, the supplier's quality system is a very important part of contractual requirements since it is directly (manufacturing, engineering, purchasing, quality control, etc.) and indirectly (marketing, inside and outside sales, etc.) responsible for the design, production, control and continued supportability of the product. Although second party audits are usually conducted by customers on their suppliers, it is sometimes beneficial for the customer to contract with an independent quality auditor. This action helps to promote an image of fairness and objectivity on the part of the customer.

THIRD PARTY AUDIT

Compared to first and second party audits where auditors are not independent, *the third party audit is objective*. It is an assessment of an organization's quality system conducted by an *independent, outside auditor or team of auditors*. When referring to a third party audit as it applies to an international quality standard such as ISO 9000, the term "third party" is synonymous with a quality system registrar whose primary responsibility is to assess an organization's quality system for *conformance to that standard* and *issue a certificate of conformance* (upon completion of a successful assessment).

Reference: "Complete Guide to CQA" (Quality America, Inc., Tucson, Arizona)
http://www.qualityamerica.com/qpproducts/cqa.htm#The%20Complete%20Guide%20to%20the%20CQA

Appendix 3

Comments on the Traceability of Unsafe Food Products

The ability to trace the distribution of a food product (traceability) requires "a process with the ability to determine a food product's route along the supply chain: from the source of the animal feedstock to the ultimate consumer who may experience injury from the unsafe meat product."

Traceability is required in order to inform people who may, or have purchased an "unsafe" product that they may be at risk of injury and also to accomplish withdrawal of any unsold inventory of the unsafe product. Traceability is also required to reduce the likelihood of repeating the sequence of events that led to the production, distribution and consumption of the unsafe product. To accomplish this requires a system that has following information:

1. The life-history of the animal that was the source of the unsafe product
2. Where, when and how products were produced from this animal, and
3. How, and to whom the identified product was distributed

Factor(s) that led to the product's unsafe condition could have arisen during any one of these three phases of the product's lifecycle and might lead to similar problems in the future.

Moreover, the ability to trace the history of a product is a factor that probably also affects the likelihood that the initial production of a food product will be 'safe', because, as Golan notes:

> *"In fact, any policy that increases the cost and probability of getting caught selling unsafe food provides producers with incentives to increase their trace-back capabilities. These types of policies will encourage the development of more efficient systems for the swift removal of unsafe foods and for investment in safer food systems—which is the ultimate objective of food safety policy."*[153]

Appendix 4

FDA's 2007 proposal on Third party voluntary audits[154]

The FDA third party proposal included in the 2007 Food Protection Plan reads as follows:

> "The universe of domestic and foreign food establishments subject to FDA inspection is immense and continuing to grow faster than the FDA's inspection resources (e*mphasis added*). Even with the most sophisticated detection tools and laboratory capabilities, the FDA's inspection resources are finite. Therefore, legislation to authorize the FDA to accredit independent third parties, or to recognize entities that accredit, to evaluate compliance with FDA requirements would allow FDA to allocate inspection resources more effectively (e*mphasis added*).
>
> To establish such an accreditation program for voluntary (emphasis added) food inspections, FDA would undertake a public process to determine best practices and solicit industry input in the design of the program. An FDA accreditation program would require FDA to accredit third-party organizations, or recognize an entity that accredits third parties. Third-party organizations could be, as appropriate, Federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest. FDA would also:
>
> - Audit the work of these organizations to ensure that FDA requirements were consistently assessed;
> - Review their inspection reports; and
> - Provide ongoing training criteria to ensure they maintain their skills and knowledge, especially as technology and requirements change over time.
>
> FDA would use information from these accredited third-party organizations in its decision making but not be bound by such information in determining compliance with FDA requirements. *Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster* review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into *consideration by the FDA when setting inspection and surveillance priorities."*

Endnotes

1 "Landmark Report Estimates Foodborne Illness Costs US $152 Billion Annually" Pew Charitable Trusts at Georgetown University http://www.sciencedaily.com/releases/2010/03/100303081834.htm

2 The Hartford Steam Boiler Inspection and Insurance Company History, http://www.hsb.com/about.asp?id=50#FINANCIAL_GUARANTEE

3 American Society of Mechanical Engineers history: http://anniversary.asme.org/history.shtml

4 CELEBRATING 125 YEARS OF ASME CODES & STANDARDS http://memagazine.asme.org/Articles/2009/june/Codes_Live_By.cfm

5 ASME Boiler and Pressure Vessel Code - 2007 Edition http://www.asme.org/Codes/International_Boiler_Pressure.cfm

6 Safety Inspection - Boiler and Pressure Vessel Safety http://www.dllr.state.md.us/labor/boil.html

7 For additional examples see the following:

a) Florida: "Administrative Weekly & Florida Administrative Code. Rule Chapter: 69A-51. Chapter Title: BOILER SAFETY "https://www.flrules.org/gateway/ChapterHome.asp?Chapter=69A-51

b) NY State Dept of Labor, Part14, Construction, installation, inspection http://www.labor.state.ny.us/workerprotection/safetyhealth/sh14.shtm#14.2

"§ 14-2.5 Inspection by insurance companies.

All boilers which are inspected by a duly authorized insurance company shall be exempt from inspection by the commissioner and by cities which qualify under the provisions of subdivision seven of section 204 of the Labor Law, under the following conditions:

(i) that the insurance company complies with the provisions of this Part;

(ii) that the inspectors of the insurance company hold certificates of competence;

(iii) that inspections by the insurance company are made at least once each year (the company writing the insurance must make provision for the annual inspection);

(iv) that the insurance company gives written notice to the owner or lessee of each boiler inspected listing all violations of any of the provisions of this Part;

(v) that a certified copy of the report of each inspection is filed with the commissioner or the inspecting agency of such city, as the case may be, within 21 days of the inspection, on such forms and in such manner as required by the commissioner or the inspecting agency of such city, as the case may be. If insurance is refused, cancelled or discontinued for the boiler inspected the report shall so state, together with the reasons therefore; the report shall also list any instances of the failure of an owner or lessee of the boiler to comply with the provisions of this Part."

c) California: Occupational Safety and Health Standards Board Subchapter 2. Boiler and Fired Pressure Vessel Safety Orders Article 5. Inspection, http://www.dir.ca.gov/Title8/779.html

8 2007 ASME Boiler and Pressure Vessel Code, American Society of Mechanical Engineers http://www.asme.org/Codes/

9 "Private Inspections and Mandatory Insurance for Managing Safety and Environmental Risks," Howard Kunreuther, Shelley Metzenbaum, Peter Schmeidler, Chapter 6, *Leveraging the Private Sector: management-based strategies for improving environmental performance*, Cary Coglianese, Jennifer Nash, (eds.) Resources for the Future, 2006

10 Introduction to Codes and Standards, page 3, ASME, http://files.asme.org/ASMEORG/Codes/About/Links/1028.pdf

11 National Board of Boiler and Pressure Vessel Inspectors**,** *Violation Tracking Statistics Released for the Third Quarter of 2009.* http://www.nationalboard.org/NationaBoardNews.aspx?NewsPageID=73

12 A series of Wharton papers discussed aspects of the role of insurance company inspections in regard to boiler regulations and examined whether insurance companies should be considered for a similar third party auditor role in a number of other areas. These papers can be accessed at http://opim.wharton.upenn.edu/risk/papers.php

(a) "Utilizing Third-Party Inspections for Preventing Major Chemical Accidents," Er, J.P., Kunreuther, H., & Rosenthal, I., *Risk Analysis* 18:145-154, 1998

(b) "Evaluating the Use of third parties to Measure Process Safety Management in Small Firms", McNulty, Patrick J. Robert A. Barrish, Richard C. Antoff, and Leon C. Schaller 1999 Annual Symposium, Mary Kay O'Connor Process Safety Center, Texas A&M University, October 26 1999

(c) “Third party Inspection as an Alternative to Command and Control Regulation”, Kunreuther, Howard C.; McNulty, Patrick J; Kang, Y., *Risk Analysis*, Volume 22, Number 2, April 2002 , pp. 309-318(10)
(d) “Managing environmental risk through insurance” Paul K. Freeman & Howard Kunreuther, Chapter 4, pp 159-189, Folmer & Tietenberg (eds.), Elgar Publishing Ltd http://opim.wharton.upenn.edu/risk/downloads/03-07-HK.pdf
(e) “The Insurance Industry as a Qualified Third-Party Auditor”, L. Collins, J.C. Belke, M. Halpern, R.A. Katz, H.C. Kunreuther and P.J. McNulty. Apr.: 31-42, *Professional Safety*, 53, pp 31-42, April 2002.
(f) “Market Based Environmental Audits and Environmental Risks: Implementing ISO 14000”, Paul R. Kleindorfer, The Geneva Papers on Risk and Insurance, 22 (No. 83, April1997) 194-210
(g) Risk-Based Pricing and Risk-Reducing Effort: Does the Private Insurance Market Reduce Environmental Accidents?”, Haitao Yin , Howard Kunreuther, Matthew W. White, Wharton Risk Management and Decision Processes Center, January 2008
http://opim.wharton.upenn.edu/risk/library/WP2008-01-31_HY,HK,MW_Risk-Based.pdf
(h) “A Firm Can Only Go Bankrupt Once; Risk Management Strategies in an Uncertain World”, Howard Kunreuther, Geoffrey Heal, 2002, Wharton Risk Management and Decision Processes Center.
http://opim.wharton.upenn.edu/risk/papersearch.php
(i) “Insurability and Environmental Risks,” Kunreuther & Freeman.
http://opim.wharton.upenn.edu/risk/downloads/archive/arch195.pdf
(j) “Private Inspections and Mandatory Insurance for Managing Safety and Environmental Risks”, Howard Kunreuther, Shelley Metzenbaum, Peter Schmeidler, Chapter 6, *Leveraging the Private Sector:* management-based strategies for improving environmental performance, Cary Coglianese**,** Jennifer Nash**,** Resources for the Future, ©2006 (k) “Use of a third party Option on Implementing EPA’s Rule on Risk Management Programs for Chemical Accident Release Prevention Programs for Propane Distribution Facilities, Isadore Rosenthal and Patrick McNulty, 11/06/1999 http://opim.wharton.upenn.edu/risk/downloads/archive/arch195.pdf
(l) “Use of an ISO 14000 Option in Implementing EPA's Rule on Risk Management Programs for Chemical Accidental Release Prevention**,** Isadore Rosenthal, Donald F. Theiler, Risk Analysis, Volume 18, Issue 2 , Pages199 – 203, April1998 Society for Risk Analysis

13 SECURITIES EXCHANGE ACT OF 1934 --2004 update http://www.sec.gov/about/laws/sea34.pdf

14 See SEC website for more information on SEC roles and functions: http://www.sec.gov/about/whatwedo.shtml

15 See sections 7,19(a) and Schedule A of the Securities Act of 1933,15 U.S.C.77g, 77s(a), 77aa(25) and (26)

16 See “Management-Based Regulation: Prescribing Private Management to Achieve Public Goals”, Cary Coglianese; David Lazer *Law & Society Review*, Vol. 37, No. 4. (Dec., 2003), pp. 691-730 and this paper’s subsequent section on the RMP regulation for a discussion of the similarities between management based regulations and self-regulatory based regulations.

17 Rule 4–01(a)(1) of Regulation S–X, 17 CFR 210.4–01(a)(1). See Accounting Series Release (‘‘ASR’’) No.150 (December 20, 1973) and ASR No.4 (April 25, 1938).

18 SEC Policy Statement reaffirming the Status of the FASB as a Designated Private-Sector Standard Setter http://www.sec.gov/rules/policy/33-8221.htm

19 Federal Register / Vol. 70, No. 236, Page 73344 / Friday, December 9, 2005 / Rules and Regulations

20 SEC registrants are entities, or entities that are controlled by entities, (a) that have issued or will issue debt or equity securities that are traded in a public market (a domestic or foreign stock exchange or an over-the-counter market, including local or regional markets), (b) that are required to file financial statements with the SEC, or (c) that provide financial statements for the purpose of issuing any class of securities in a public market.

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"Section 3.3.2 of the paper contains the following paragraph:
"3.3.2. Vagaries of the Rule with regard to Programs and Plans
Getting agreement between individuals on what constitutes good faith implementation of the management system elements of the rule depends on having shared definition of terms such as expertise and timeliness. These terms are not defined and in fact are difficult to define operationally."
The paper then cites specific examples of undefined terms in dome of the sections of the published RMP Rule that provide the basis for this summary statement:
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141 See Buzby et al., *supra* note 23, at 11 ("High transaction costs and information costs dissuade food-poisoning victims from filing lawsuits, limit feedback to firms to produce safer food … the result is a level of food safety that is less than the socially optimal level provided by a perfectly competitive market.")

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g) "Risk-Based Pricing and Risk-Reducing Effort: Does the Private Insurance Market Reduce Environmental Accidents?" Yin, Haitao, Kunreuther, Howard and White, Matthew (September 9, 2008). SSRN: http://ssrn.com/abstract=1265592 or http://bpp.wharton.upenn.edu/mawhite/papers/USTRisk.pdf

h) "A Firm Can Only Go Bankrupt Once; Risk Management Strategies in an Uncertain World", Howard Kunreuther, Geoffrey Heal, 2002, Wharton Risk Management and Decision Processes Center**,** http://opim.wharton.upenn.edu/risk/papersearch.php

i) "Insurability and Environmental Risks" Kunreuther & Freeman,

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j) "Private Inspections and Mandatory Insurance for Managing Safety and Environmental Risks, Howard Kunreuther, Shelley Metzenbaum, Peter Schmeidler, Chapter 6, *Leveraging the Private Sector:* management-based strategies for improving environmental performance, Cary Coglianese**,** Jennifer Nash**,** Resources for the Future, 2006

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148 "THE POTENTIAL FOR RECALL INSURANCE TO IMPROVE FOOD SAFETY", Skees, Jerry R., Botts, Aleta, Zeuli, Kimberly A., Vol. 4, 2001, pp 99 – 111

149 "Product Liability, Insurance and the Private Regulation of Food Safety", Tetty Havinga**,** (Working Paper Institute for Sociology of Law, Radboud University Nijmegen, (An earlier version of this paper was presented at the 2007 International Conference 'Law and Society in the 21st Century', Berlin, July 25-28. October 2007) Page 4

"Product liability law is thought to have potential impact on how food firms manage food safety and food hygiene. This could theoretically work in three ways (see fig 3).

1. The influence of product liability on business risk management may be indirect, through litigation. Claims from injured consumers or damaged business relations may influence preferences and costs of firms, inducing businesses to assure food safety to prevent liability claims. The threat of lawsuits serves as a stimulus to the industry to improve practices. This is a special effect of liability law.
2. A second indirect route is through insurance. Firms may cover the risks of a liability claim by insuring this risk. Insurance companies may induce food safety controls (through the terms of insurance policy or by calibrating premiums according to the level of precautions taken). However, insurance could also limit the economic incentives for firms to produce safe food by taking over the financial risk. The impact of insurance companies can be either a special or a general effect of liability law (i.e. related to a particular claim or not).
3. Finally, liability law may influence business management strategies directly, inducing businesses to assure food safety. We could call this the general effect of product liability law. I will shortly discuss each of these three possible influences of product liability law on food safety measures by food industry."

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151 "NATIONAL CONFORMITY ASSESSMENT PRINCIPLES FOR THE UNITED STATES" http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/NCAP%20second%20edition.pdf

152 International Organization for Standardization. 1996. *ISO Guide 2*. Geneva.

153 Elise Golan, Barry Krissoff, Fred Kuchler, Kenneth Nelson, Gregory Price, and Linda Calvin (2004). Traceability in the U.S. Food Supply: Economic Theory and Industry Studies, Agricultural Economics Report, Number 830, Economic Research Service, USDA.

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