Food Safety Performance Through HACCP; Regrets & Opportunities

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INTRODUCTION

The Hazard Analysis and Critical Control Point (HACCP) system was first presented to the U.S. Federal Drug Administration (FDA) in 1971 by food safety professionals from The Pillsbury Company, led by Dr. Howard Bauman, head of research, food safety and regulatory affairs, HACCP was offered as a means to assure safety of foods produced for the U.S. space program (Sperber and Steir, 2010). The principles underlying HACCP have their origin in an engineering tool from the 1950's that was used in non-food industries to systematically and critically assess how a process could fail, and the causes and effects of a failure. Failure Mode and Effect Analysis -- or FMEA is today used in many industries where failure of a process, system or product must be mitigated, -- and HACCP, a tool closely related to FMEA, have become the centerpiece of most modern food safety management systems worldwide. Since the initial creation of HACCP in the 1970's there have been many scholarly papers written, regulations promulgated, lectures given, and expectations raised on this topic. This paper will not attempt to provide an exhaustive review of the theory and principles of HACCP or the literature supporting that theory. However, given that the past 40 years have seen considerable approval for the risk-based concepts described in HACCP, worldwide adoption of HACCP systems, and some controversy surrounding its ability to mitigate foodborne illness, it is a worthwhile topic for ongoing debate and dialog. As the food industry faces the incredibly daunting task of safely feeding a burgeoning worldwide population that will grow to 9.6 billion by 2050, an increase of 2.4 billion people over the next in 36 years (UN, 2013), the approach the food industry uses to produce food safely must be actively debated and improved if we have any chance of meeting this challenge. This paper will provide historical perspective and suggestions for the future, drawn from practical experience of respected industry, government and academic food safety thought leaders (Expert Panel*), as well as government publications and scientific publications.

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A BRIEF BACKGROUND

HACCP was originally developed by the food industry, with the intent that it would be a voluntary methodology used by industry to manage food safety risks in certain categories of food. It gained some traction in the early years, primarily in food categories that had been deemed to have a higher risk profile either due to known risks or a history of causing foodborne illness. In 1985, a technical expert committee of the National Research Council of the National Academy of Sciences published a report titled "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients" which became widely known as the "green book". The expert committee report described HACCP as the most effective means of ensuring food safety and they stated that HACCP would have to be made a regulatory requirement to ensure widespread use. (Surak, J.G., 2009).

Not long after this publication, in 1988 the National Advisory Committee for Microbiological Criteria for Food (NACMCF) was established to advise, amongst others, the U.S. Department of Agriculture (USDA) and FDA on critical matters related to the scientific basis for controlling microbial hazards in food. Out of this advisory committee's early work came today's well known and established 7 Principles of HACCP (Hulebak and Schlosser, 2002). The work by NACMCF was founded on the early principles defined by the Codex Alimentarius Committee, who after the creation of the 7 Principles by NACMCF, adopted these principles with some minor tweaks in its 1997 Codex standard titled *"The Hazard Analysis and Critical Control Point System and Guidelines for its Application"* (Sperber, 2005).

The mid-1990's was an era of several very significant and high profile foodborne outbreaks and the food industry, particularly the meat industry, came under intense scrutiny. Industry groups and consumer advocates alike publically characterized the traditional meat and poultry inspection system as overwhelmed by the practical reali-

Table 1. 7 Principles of HACCP (Codex, 1997)

No.	Principle
1.	Conduct a hazard analysis
2.	Determine the Critical Control Points (CCPs).
3.	Establish critical limit(s).
4.	Establish a system to monitor control of the CCP.
5.	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
6.	Establish procedures for verification to confirm that the HACCP system is working effectively.
7.	Establish documentation concerning all procedures and records appropriate to these principles and their application.

ties of modern, high volume meat and poultry slaughter and processing. Recognizing this reality, the industry and government worked cooperatively to improve the system. As a major pillar of the response, the USDA published the *"Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (HACCP)"* Rule in 1996 (Hulebak and Schlosser, 2002). This rule made HACCP mandatory for all federally inspected meat and poultry processing plants in the U.S.

The Canadian food industry and regulators were also faced with challenges during this era and followed a similar regulatory path with the first step to mandatory HACCP taken in 1992 when the *"Quality Management Program",* a HACCP-based program was made mandatory for all federally registered fish processing establishments in Canada (Gagnon, et al., 2000). This requirement was followed by the Food Safety Enhancement Program (FSEP) in 1994 leading to the requirement in 2005 for all Canadian federally registered meat and poultry producers to adopt HACCP as per FSEP guidelines (Herath and Henson, 2006).

Many experts have commented on the unintended consequences of a regulatory mandate for HACCP versus voluntary industry adoption. The mandatory approach and the nature of its regulatory inspection requirements overlaid a new dimension to the methodology that was not anticipated by those early HACCP pioneers. This nuance led to some early missteps in the application of HACCP principles. Many of these early gaps could be partly attributed to the nature of the regulatory framework, including the historical organizational structure, existing norms for inspection of facilities against compliance to standards, regulatory and industry employee knowledge and skill with HACCP, and the historical relationship between the regulated operator and the regulator. Underlying these gaps was a significant clash between the regulator's organizational culture and the scientifically based HACCP approach that was designed to focus on the critical few hazards. The Codex Alimentarius Committee anticipated some of these challenges and provided guidance for countries adopting mandatory HACCP in their original guideline document in 1997 (Codex, 1997). Bernard (1998) reported a list of the most frequently found issues with HACCP systems during the early phase of adoption in the early 1990's:

- Hazards were not adequately identified;
- Critical Controls that do not address safety concerns;
- Plans that lack CCP's that are warranted for safety;
- Identification of operating limits as Critical Limits;
- Critical Limits not adequate or supported by scientific studies;
- Corrective actions cited not addressing the product involved in a deviation.

These are symptoms of poor implementation of the basic principles of HACCP. Unfortunately, almost 20 years after HACCP became mandatory these types of deficiencies remain all too common. Based on British Retail Consortium (BRC) third party audit findings, deviation to the HACCP system was found to be first on the list of most non-conformances globally (Braxton and Kelley, 2013). This was found consistent across audits conducted in Canada, the U.S. and Mexico since the introduction of Section 2, "*The Food Safety Plan – HACCP*" into the BRC Standard in 2011. Table 2 shows that about one third of sites audited had 2 or more HACCP non-conformances and the average HACCP non-conformances is about 1.5 per site across North America. Some of the non-conformances of today may be less critical than those found in the early years; nonetheless 20 years after mandatory HACCP in North America, gaps remain. The BRC analysis demonstrates that constructing and verifying flow diagrams and conducting adequate hazard analysis were the top areas for non-conformance.

Table 2. 2012 BRC third party audit non-conformances (NC) specific to HACCP (Braxton and Kelley, 2013)

	BRC audits with a HACCP NC (%)	HACCP NC's	Avg HACCP NC's per site where HACCP NC's occur	Sites with 2 or more occurrences (%)
Canada	434	237	1.5	37
USA	36	665	1.45	32
Mexico	53	43	1.5	31

Bernard (1998) made the following insightful observation concerning the execution of regulated and mandated HACCP: "How we educate industry and regulatory officials prior to implementation and how effective we are at achieving the needed culture shift may well be the difference between the slow, and probably difficult, march to the next level of food safety or a train wreck."

THE VALUE IS CLEAR—SO ARE WE REAPING THE BENEFIT?

Experts largely agree that HACCP has improved food safety performance for some sectors of the industry. While it is not possible to accurately separate the effects of HACCP adoption from other important changes in the industry—such as new food safety technologies, modernized and hygienically designed equipment and facilities, improved packaging, and other non-HACCP related improvements—most argue that HACCP brought a more systematic approach to understanding the inherent risks in a given food process. Some on the expert panel believe that improvements from HACCP can be seen directly in historical microbial pathogen trends and for certain reportable foodborne illness data. Table 3 demonstrates significant improvements in three of the four major foodborne pathogen related illnesses tracked by CDC in the U.S., whereas Salmonellosis is the foodborne illness trend that has actually increased during the period from 2000 to 2012.

Some on the expert panel believe that a portion of the improvement in Listeriosis, E. coli O157 illness and Campylobacterosis rates can be directly attributed to the fact that HACCP brings visibility to foodborne risks and the need to exert control Many agree that the introduction of HACCP has raised the general awareness of food hazards and the science behind controlling these hazards; however, they are quick to point out that on its own, HACCP has not improved food safety performance and cannot be seen as a stand-alone program. There is no doubt that HACCP must be seen as an integrated part of the end-to-end food safety management system including prerequisite programs, Good Manufacturing Practices (GMPs), routine auditing, general facility and employee hygiene, and most importantly the food safety culture of the company including senior management commitment. This last point, company culture, is an area we will explore further in this paper.

THE CRITICALITY OF SENIOR MANAGEMENT COMMITMENT—A DRIVER FOOD SAFETY BEHAVIOR

So the question remains, are we reaping the benefit of the last 40 years of HACCP learnings and do we have the courage to learn from our regrets? In 2001, Mortimore (2001) published findings in a paper titled *"Problems Encountered Applying HACCP Approach to Food Safety."* In summary, problems were found to lie more in culture and attitudinal factors related to people and their behaviours than in the actual HACCP system. Mortimore goes on to describe challenges with each of the 7 Principles (Table 1) and linking challenges in each principal back to having the right people, with the right knowledge and attitudes, directly involved in designing and maintaining the HACCP system. Reasons for not implementing, maintaining and updating HACCP systems are not simply explained in terms of regulatory hindrance or unwillingness by manufactures, the explanation also includes the acknowledgement that presence of technical barriers may impede the application of the system. These barriers includes all those practices, attitudes and perceptions that negatively affect the understanding of HACCP and consequently lead to improper and ineffective implementation and maintenance of the 7 Principles (Panisello and Quantick, 2001).

The concept of underpinning HACCP adoption with senior management commitment is not new, as the point was made in multiple publications including the original Codex Guidelines document for the application of HACCP in the late 1990's. The preamble of this guidance includes the following quote: "The successful application of HACCP requires the full commitment and involvement of management and the work force" (Codex, 1997). Unfortunately, this appears to be the only direct mention of its importance in this guideline document. Management commitment cannot be limited to the top floor in the corporate office building. Management commitment starts with the first line of defense, the front line supervisors, who steer the ship on a daily basis with respect to food safety practices and decisions. Managers are responsible for understanding the pinpointed desired behaviours that need to be supported and adopted by everyone operating in the end to end processes of producing food. Changes throughout an organization can be characterized on

Table 3. Illness incident rate by pathogen; objective, actual and % change (AMI, 2013; CDC, 2013)

Pathogen	Healthy People Objective, 2020*	2011 Incidence Rate*	% Change in Incidence Rate (2000-2012)
STEC O157	0.6	0.98	(45%)
Listeria	0.2	0.28	(24%)
Salmonella	11.4	16.47	+17%
Campylobacter	8.5	14.31	(7%)

*Incidence rate = cases per 100,000 population

a progressive maturity model as described in Table 4. A guide such as this can be tailored to the organizational culture, and should be in place as a means to monitor organizational progress toward internalizing a culture of food safety.

Too often perception is that documenting a system is what will make HACCP work (Mortimore, 2001). While documentation is a necessary requirement, senior management must recognize that greater emphasis needs to be placed on developing and maintaining a food safety culture that includes rituals and tactics such as frequent communications about the importance of food safety, visual management of critical food safety metrics to those on the shop floor, and in-depth training on validation and verification of HACCP systems. Inclusion of all stakeholders along the food supply chain—including regulatory agencies—rather than just the manufacturing team - will ensure the effectiveness of the HACCP system. Early recognition and adoption of high quality training on Food Safety Management is noted by the Expert Panel to be an important enabler of effective HACCP systems.

Lack of awareness of the HACCP principles as one of the technical barriers was found to restrict adherence to the principles in U.K. food processing establishments. It was reported that despite the wide dissemination and scientific support of its principles, successful HACCP implementations were limited. This is of no surprise to behavioral scientists who recognize that the mere existence of a scientifically valid system of food safety management, despite a worldwide escalation of foodborne disease, would not guarantee its use (Griffith, et al., 2010).

TRAINING—A CRITICAL ANTECEDENT TO SUCCESSFUL HACCP ADOPTION

One of the key factors to identifying and supporting the desired behaviors (Table 4) while developing and maintaining a HACCP system is in knowing what to do. Assessment of post-training HACCP knowledge and its use as a predictor of effective development and implementation of HACCP was studied by Wallace et al. (2005). The majority of sites in the study were found to have marginal knowledge in the first three principles of HACCP; hazard analysis, CCP identification, and setting critical limits. In this study, assessment of knowledge related to implementation this was found to be poor and it is reasonable to expect this lack of knowledge would lead to both weak HACCP system development and implementation. All sites in the study predicted, based on the knowledge assessment, to have unsafe HACCP systems implemented (Wallace et al., 2005).

Training materials and programs are available for small and large organizations and in many cases training is diligently provided to staff to comply with regulatory requirements and customer expectations. However, companies and regulators can erroneously believe it is sufficient to simply train staff on HACCP to meet regulatory compliance trusting that this will make them "best-in-class" with respect to implementing and operating HACCP systems. Few, if any food companies, test the knowledge comprehension and correlate this to the effectiveness of their HACCP systems. Even fewer conduct behavioural studies to ensure that this knowledge leads to desired behaviours. This is unfortunate as this type of rigor around assessment of the effectiveness of can be a useful predictor of an internalized food safety culture (Huffman and Jespersen, 2012).

Formal requirements for HACCP training would need both global agreement on necessary knowledge and skills for personnel involved in HACCP at all levels, as well as learning outcomes for training programs. This is better developed in some parts of the world than in others, but there is still no global agreement and no global standards for HACCP training or much less, unified and accredited certification of trainees. Although uptake of HACCP training has been good for many companies, better requirements for HACCP training within legislation along with multinational recognized schemes, would make HACCP competence more widespread and could serve to improve the knowledge and skills of HACCP teams.

COMPANY CULTURE AND REGULATORY HACCP MUST COEXIST

Bernard (1998) predicted the importance of culture in his paper on HACCP in a post-regulated world, and his prediction has certainly proven true. When a company first embarks on adopting HACCP in their operation, the first iterations are typically rudimentary and result in little more than a written plan. In the early 1990s, when HACCP was first adopted by meat and poultry companies, the primary goal by many was simply to complete the written plan prior to the regulatory deadline established. Early adoption did very little to make food safer in those early years, as satisfaction came in knowing that the regulatory requirement was met, unfortunately for many companies that was the destination and they ignored the need for continuous improvement.

Over time, adoption of HACCP has forced companies to think about their operations in a risk-based way, using multidisciplinary knowledge and science-based viewpoints to identify necessary controls. The power of the preventative nature of HACCP cannot be understated, but this can only work where it is properly applied and supported, as well as updated and improved on a continuous basis. A major challenge for the food industry includes overcoming the complacency that comes with the "we've already done HACCP" attitude that plagues many players in the industry. Frequently it has been observed and documented that there is a lack of knowing how well HACCP systems are working: companies just have awareness that one has been developed (Wallace, 2013).

Attitudes, behaviors and company culture have been cited by many as critical factors to successful implementation and improvement of HACCP and its supporting programs. So why has the concept been poorly adopted

Table 4. Examples of desired behaviours across operational roles and organizational maturity levels

	Qualitative Description of Organizational Maturity Level				
Role	**"Doubtful"**	**"Aware"**	**"Knowing"**	**"Enlightened"**	**"Internalized"**
	Who messed up?	*How much time will it take?*	*"Just fix one problem at a time"*	*"What does the data tell us?*	*"How does this fit in to long term plans?"*
Front line supervisor	No comprehension of the food safety plan.	Understands that the food safety plan brings value and accepts this as long as it does not require time.	Learned through crisis or culture shift that the food safety plan is mandatory. Becomes supportive of FSQ peers.	Participates in food safety plan activities to collectively improve food safety performance.	Food safety decisions are part of running an effective, safe shift fully integrated into the manufacturing system.
Plant manager	A problem with the food safety plan gets blamed on the FSQ leader at the plant.	The food safety plan is seen as necessary as long as it does not require any money or time from operations staff at the plant.	Learned from top down pressure that the food safety plan have to be part of the plants priorities. Openly mentions FSQ staff and their importance to plant performance.	Seeks to connect food safety performance to plant performance.	Food safety decisions are part of the plant budgeting, review and prevention discussions based on data are integrated into the manufacturing system.
Sr. VP Operations	The food safety plan is not seen as a management tool.	The food safety plan is not considered when budgeting time or money.	Dictates down the chain the priority of the food safety plan. Collaborates with FSQ peers in open communications.	Sets out directions on participation and performance measures for food safety.	Food safety prevention is systemically managed through data and integrated into the manufacturing systems.

Source, internal document, Maple Leaf Foods, 2013.

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in many companies as recent foodborne outbreaks would suggest? The answer lies partly in the regulated and mandatory nature of the program. Regulation is most commonly viewed as a minimum standard that everyone in industry must meet. Regulations are compliancy-based in nature and rarely incent industry to "go above and beyond". Furthermore, the concepts of continuous improvement are virtually impossible to regulate and a true state of internalization (Table 4) can be difficult to reach. Regulations also rarely instill an entrepreneurial spirit that can lead to innovation and new ways of solving problems. Quite the contrary, regulatory mandates encourage minimum compliancy, stability and status quo.

The premise upon which HACCP was founded was that each establishment's plan(s) would be specific to their operation. This has been difficult for regulators to accept and implement, since a regulatory agency is looking for uniformity Frontline inspectors who move from one plant to another may not readily understand the underlying principles of HACCP and end up spending a lot of time and energy trying to get them to look alike across the board. The Expert panel believes that better training of inspection personnel charged with food industry oversight must be delivered and designed to help the regulator properly assess the food safety hazards and understand how to apply the principles of HACCP.

SUMMARY AND CALL TO ACTION

Food Safety requirements on the industry are ever increasing as we look to safely feed an additional 2.4 billion people in the next 37 years:

- HACCP systems are in place throughout much of the North American food industry and have resulted in increased awareness of risk and general improvement in the approach to managing risks; however, it is questionable if the potential of HACCP as a risk mitigation tool has been maximized.
- **Action - Industry must commit to continuous improvement of food safety plans.**

HACCP is the centerpiece of a robust food safety system, and the entire system must be considered in context for HACCP to be successful at preventing foodborne illness;

- HACCP is an expert system and many plants do not possess the in-house expertise to maintain and continuously improve systems (Expert Panel, 2013).
- Having a written plan is not enough. The system must be dynamic, and should be lean in nature and efficient; and most importantly, it must be managed by a HACCP team with diverse experience and in-depth technical knowledge.
- **Action: Industry, academia and government must re-commit to the concept that every HACCP plan requires a person or persons with in-depth technical and practical applicable HACCP knowledge.**

HACCP and the supporting Food Safety System that includes all preventative controls does not work without complete senior management commitment.

- With complete senior management commitment from the top, a food safety mindset can thrive and grow in any company culture; however, without that commitment, a food safety plan will eventually fail with catastrophic consequences for the company and public health.
- Culture is the combination of attitudes and behaviors and when this is right, food safety improvements will occur.
- Culture can be either an enabler, or derailer, of HACCP and preventative controls. Without the right culture, the firm will eventually experience a food safety crisis.
- **Action: Industry must embrace the need to drive behavioural change from the most senior positions and engage in deciding desired behaviours and methods of managing positive and negative consequences to reinforce food safety culture across all roles and levels of the organization.**

The authors wish to extend a very special thank you to the Expert Panelists who took time from their busy lives to provide their regrets and opportunities gathered through years of experience with designing and implementing HACCP.

Expert Panel consists of (in alphabetical order):

Bruce Tompkin Ph.D.; Carol Anne Wallace Ph.D.; Colin Dennis Ph.D.; Dane Bernard; Dave Theno Ph.D.; David Acheson, M.D.; Dean Danilson, Ph.D.; Jim Hodges; John Weisgerber; Mansel Griffith, Ph.D.; Russell Cross, Ph.D. and Sara Mortimore.

A special thank you to Bruce Tompkin, Ph.D. who provided a significant number of historical documents cited in this paper and Peter Slade, Ph.D. who provided review and technical editing.

REFERENCES

BERNARD, D. 1998. Developing and Implementing HACCP in the United States. *Food Control*, Vol.9, No. 2–3, pp. 91–95.

BRAXTON, D. KELLY, T., 2013. State of Nation Report, British Retail Consortium (BRC), Food Safety Americas Conference, Orlando, FL.

CODEX, 1997. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application. *Annex to CAC/RCP 1-1969, Rev. 3*.

GAGNON, B., MCEACHERN, V. and BRAY, S., 2000. The role of the Canadian government agency in assessing HACCP. *Food Control*, **11**(5), pp. 359-364.

GRIFFITH, C.J., LIVESEY, K.M. and CLAYTON, D.A., 2010. Food safety culture: the evolution of an emerging risk factor? *British Food Journal*, **112**(4), pp. 426-438.

HERATH, D. and HENSON, S., 2006. Does Canada need mandatory HACCP? Evidence from the Ontario food processing sector. *Canadian Journal of Agricultural Economics/Revue canadienne d'agroeconomie*, **54**(4), pp. 443-459.

HUFFMAN, R.D. and JESPERSEN, L., 2012. Building Food Safety into the Company Culture. 58th Internaltional Congress of Meat Science and Technology, August 16–18, Montreal, Quebec, Canada.

HULEBAK, K.L. and SCHLOSSER, W., 2002. Hazard Analysis and Critical Control Point (HACCP) History and Conceptual Overview. *Risk Analysis*, **22**(3), pp. 547-552.

MORTIMORE, S., 2001. Problems encountered applying the HACCP approach to Food Safety. *AJHM*.

PANISELLO, P.J. and QUANTICK, P.C., 2001. Technical barriers to Hazard Analysis Critical Control Point (HACCP). *Food Control*, **12**(3), pp. 165-173.

SPERBER, W.H., 2005. HACCP and transparency. *Food Control*, **16**(6), pp. 505-509.

SPERBER, W.H. AND STEIR, R. F., 2010. Happy 50th Birthday HACCP: Retrospective and Prospective. Food Safety Magazine, Dec. 2009 – Jan. 2010.

SURAK, J.G., 2009. The Evolution of HACCP. A perspective on today's most effective food safety systems. Feb-Mar. Food Safety and Quality magazine.

WALLACE, C.A., POWELL, S.C. and HOLYOAK, L., 2005. Post-training assessment of HACCP knowledge: its use as tive HACCP development, implementation and maintenance in food manufacturing. *British Food Journal*, **107**(10), pp. 743-759.

United Nations, Department of Economic and Social Affairs, Population Division, 2013. World Population Prospects: The 2012 Revision, Key Findings and Advance Tables. Working Paper No. ESA/P/WP 227.