

Hazard analysis and critical control point—original “spin”

Catherine E. Adams *

General Manager, Quality Assurance, Heinz North America, 1062 Progress Street, Pittsburgh, PA 15212, USA

Received 20 April 2001; received in revised form 6 March 2002; accepted 7 March 2002

1. Introduction

It may be a reflection of age, but I hope it is a reflection of age and wisdom that we have been invited to present a “retrospection” on hazard analysis and critical control point (HACCP) as a regulatory tool. HACCP has become a regulatory tool of choice for many countries, advanced through its adoption by the Codex Alimentarius Commission in the early 1990s. HACCP has been defined as a method for ensuring food safety since the late 1960s. HACCP became recognized and widely endorsed in the 1980s and in the 1990s through its adoption by the US Department of Commerce for seafood, US Department of Agriculture for meat and poultry, and US Food and Drug Administration for other foods, including juices. It has been a bumpy road for this food safety tool. But HACCP is “innocent”. As a food safety methodology, it is sound and effective. HACCP may wish that we had left it alone in the 1980s. But we brought this food safety method into the spotlight and told it that it should be a “star”. We adorned it through public hearings, public meetings and workshops, and countless private debates. We built this new tool, HACCP, into an old machine—a bureaucracy, and we are surprised that more than a decade later we are still debating some of the same issues . . .

It is my job to remind us why we started down this road; and why, in the beginning, we pursued HACCP and created its “original spin”.

2. In the beginning

My stake in HACCP began in 1988. I had joined the Food Safety and Inspection Service at USDA and was fortunate enough to be working with the Administrator, Dr. Lester Crawford. We received recommendations for the adoption of HACCP from the National Academy of Sciences (Subcommittee on Microbiological Criteria for Foods & Food Ingredients, 1985), which was then and remains a most respected scientific body. Not once, twice or three times—but four times beginning in 1985, the NAS recommended that the Federal regulatory agency for meat and poultry initiate a new manner of inspection. They recommended that the Agency abandon traditional methods of inspection that focused on “floors, walls and ceilings”, and commence a more scientifically based inspection process that took into account the primary risks to public health. This science-based approach considered those threats to food safety that were most likely and required that plans be in place to avoid them. This plan was recognized as the HACCP system. The HACCP system was based on a simple and logic-driven sequence of events (Pierson & Corlett, 1992):

- conduct an assessment of risks,
- identify critical control points,
- identify critical limits,
- identify monitoring activities,
- identify corrective actions with accountabilities,
- identify record keeping,
- verify that the system is working.

HACCP had been launched in the era of early space travel by the Army Natick Laboratories, NASA and the Pillsbury Company. The National Marine Fisheries

* Tel.: +1-412-736-4746; fax: +1-412-237-3927.

E-mail address: catherine.adams@hjheinz.com (C.E. Adams).

Service had initiated HACCP's use in its voluntary program for seafood inspection and was having relative success in this complex business. It was time to either adopt such a strategy for meat and poultry inspection, or come up with a good explanation for continuing to evade the consistent recommendations of scientifically based and honorably charged bodies, like the NAS.

Had we been burdened with the knowledge and wisdom of another decade of experience as “change agents”, we may have danced around the issue for a couple of years, waited for an administration change or waited for others to take the front-line offensive. Instead, I believed and similarly, Dr. Crawford believed that the time was right. It was time to start a new order of things. It was time to start the evolution towards a new method for meat and poultry inspection. However, it is good to remember and be forewarned of what Machiavelli said about forming new orders (Machiavelli, 1998):

It may be considered that there is nothing more difficult to carry out or more doubtful of success, nor more dangerous to handle than to initiate and new order of things For the reformer has enemies . . . and their adversaries who have laws in their favor . . . and the incredulity of mankind who does not truly believe in anything new until they actually experience it.

Instead, out of courage or out of ignorance, we began the process that has consumed us all for more than a decade. We have changed the way that meat and poultry inspection was performed everyday in more than 7000 Federally inspected establishments. We made the decision that we use HACCP instead of floors, walls and ceilings traditional inspection, knowing fully well that this would enhance the public health and well being. And I believe at this time, that we were right.

3. The process

To facilitate change requires a large cast of motivated individuals with vested interest and “something in it for them”. The players included the constituents of the Federal inspection process: the industry, the inspectors, consumer interest groups and the Congress. The strategy was to gain acceptance for the vision—this was the “right thing to do”, then to develop the process through collaboration with the goal being consensus and support for HACCP as a regulatory inspection tool.

The benefit of HACCP was viewed as a means to empower (or demand) the industry accept responsibility for understanding and preventing food safety risks (Subcommittee on Microbiological Criteria for Foods & Food Ingredients, 1985). HACCP emerged near the end of the era of “Quality Control”, where some believed

that “inspection” was the way to assure food safety. The notion of “Quality Assurance” was coming to the forefront. The difference between Quality “control” and “assurance” is the intent to build Quality into the process of manufacturing, rather than find the failures at the end of the run. We now know only too well that it is not possible to inspect our way to Quality or food safety. The product must begin with the process in mind, and be designed to achieve whatever attributes are desired—including food safety.

It was recognized that change for the inspection process would only come through the support and collaboration of all interested parties. We initiated a process that included collected information about needs and concerns, through:

- public regional meetings,
- workshops with the industry held across the country,
- meetings with consumer groups,
- meetings on Capitol Hill,
- meetings internal to the Agency with representatives of our inspector unions and professional groups,
- meetings with other Federal and state agencies.

It was a case of “regulation in the sunshine”, and the process was designed and intended to take all concerns into account. Our six-member “Core Team” that led this process was interdisciplinary and included a representative from the inspector's Union. We identified the issues that need to be addressed and resolved for us to achieve success. These included:

- training for the industry,
- training for the inspectors,
- special consideration for small businesses,
- potential trade impact for export and import businesses,
- prerequisite programs,
- validation methodologies,
- differentiating food safety from Quality issues,
- record-keeping concerns,
- gaining consumer understanding and acceptance,
- overcoming the machinery of human nature—the resistance to change given the “comfort” of status quo.

4. An evaluation in retrospect

How well did we do? If one measure of success is the incorporation and amalgamation of an idea, then we have been brilliant. HACCP has been adopted into the international vocabulary of food safety. The “seven principles” of HACCP (Stevenson & Bernard, 1999) read now like the Ten Commandments for manufacturing safe food. HACCP, which started as an idea between

Howard Bauman of Pillsbury and NASA, has permanence and a legacy that will not be erased (Pierson & Corlett, 1992). HACCP has been recognized worldwide as a great idea and a great tool for understanding and achieving food safety.

But how have we done as a regulatory tool? May be not so well.

Where have we stumbled? This is not for me to judge, but let me offer three perspectives.

(1) *Despite the widespread publication and relative crystal clarity of the seven-step process, we have inconsistent execution by the industry and the agencies:* Is training at fault, or is this manipulation of the process to best service self-serving agendas? Certainly training for the industry and the agencies is essential. The Government Accounting Office (GAO) suggests that FSIS inspectors need more training regarding roles, responsibilities and authorities for reviewing HACCP plans and microbial testing (Government Accounting Office, 1992). The GAO also suggests that there needs to be greater clarity around the issue of noncompliance notices and evaluation of HACCP's effectiveness (Government Accounting Office, 1992).

That training is important for all parties is clear. "How much is enough?", is not so clear. The original intent was for inspectors to understand the process for manufacturing and distributing food, just as the industry does in performing these tasks on a daily basis. Was this naïve on the regulator's part to expect those who have never worked in the industry arena to understand the processes and the risks equally with their industry partners? The pressure from consumer groups on the regulators to act with authority and the power of onerous enforcement may preclude the agencies' representatives from gaining full knowledge of food manufacture and distribution. The original intent was never to "put the fox in charge of the hen house". However, the expectation was that the foxes and the hens could talk to and learn from one another without the appearance of either one being co-opted or compromised.

(2) *In making HACCP a regulatory program, the door is open for regulatory vulnerability and liability:* The industry has developed plans in some cases with one or no CCPs. Is this correct? Who is to judge? Certainly there are some products and processes that may not have critical control points. There are other products and processes that should have several.

Are we as an industry excessively concerned about record keeping that we have thrown the proverbial baby out with the bath water? Are we so concerned by regulatory oversight that we are collecting two sets of records—one for the austere HACCP plan that we share with regulators and one for the food safety and Quality assurance programs we use to run our businesses?

Clearly, the industry is counseled by some of the best food attorneys, including Rick Silverman of Hogan

and Hartson, to avoid records that "can come back to haunt you" (Silverman, 2000). Among Mr. Silverman's prudent cautionary recommendations include to avoid cost-benefit evaluations in risk assessments. This is equivalent to placing a value on human life, which is never a "good sound byte" in court or the media. He also counsels against the development of draft risk assessments. He suggests discussing recommendations orally before committing thoughts to the written word (Silverman, 2000). Why? Because it is possible to record some incriminating, albeit preliminary, thoughts; such as first considering a risk as serious, then discounting it later as insufficient to rate a "CCP" status. I have learned to listen to Mr. Silverman's advice over the years. He is usually right. However, the result may be that HACCP plans are developed with lawyers present instead of scientists. This was not the original design.

(3) *Food safety is not a "one-act play". HACCP is only part of the planned events and processes required for food safety, regulatory compliance and customer satisfaction:* HACCP was designed as a process for prioritizing and controlling those risks most likely to occur. It is not about zero risk and not about guarantees. HACCP is not a magic wand nor magic bullet. Even the best and most elegant HACCP plan is still prone to human error and failed execution. There must always be additional controls in place for food manufacturers.

Have the agencies and consumer groups given too much attention and focus to HACCP in the last decade? There has also been attention for prerequisite programs and the establishment of sanitation standard operating procedures (SSOPs). The original intent for HACCP never contemplated regulation exclusively by HACCP programs. Once again, the objective was to make the industry think about the risks that were inherent to the manufacturing process and insist on implementation of methods to control those risks, rather than count on an inspector to find and correct problems. HACCP was to be part of a matrix of regulatory controls, but it was a sign of a cultural shift to a more educated, knowledgeable and flexible inspection process. The original intent was for an inspection process of the future to be able to discern the "necessary" from the "nice", focus on the desired results for that which was truly important, and enable different methods for getting to that end point. If there were scientific data that proved the safety of a given process, that process could be allowed vs. being precluded by prescriptive regulations. A "HACCP approach" to regulation adopts a different mentality to the inspection process. It is a "thoughtful" approach that keeps focus on the target, but recognizes that there is more than a single way to get there. Yes, this approach gives advantage to those manufacturers willing and able to understand their manufacturing and distribution processes. For those not willing to do so, a more prescriptive method would be available. This was the orig-

inal design that could have provided a win–win scenario for the consumers, the industry and the agencies.

The notion of performance standards fit within this model. There is nothing wrong with establishing the end point for an effective process. The only question that remains is whether or not the performance standards that have been adopted are required for public health. Happily, the search for the answer to this question is outside the scope of this author's given topic.

The best solution for consumers is for food manufacturers to know their products and their processes and take charge of ensuring food safety and Quality performance. HACCP will always be a tool in our toolkit, but HACCP cannot function in isolation. In practice, for food safety systems to be fully effective, they should be embraced by manufacturing systems that affect a culture. A culture is more a subject of psychology than it is prescription. A "safe food culture" provides for an operator on a line in a manufacturing plant who:

- knows what his or her job is,
- understands their personal role in food safety and customer satisfaction,
- knows they have their management's support to do the right thing, and
- cares enough to do it everyday.

Creating or maintaining a culture requires a dynamic and multi-faceted approach. A culture is not subject to regulation and cannot be regulated in a traditional sense—it needs to be inspired.

5. Conclusion

In the beginning, we knew that HACCP was a great idea as a regulatory tool. Time has proven that the decision to move ahead with HACCP was a good choice. HACCP has provided the platform for a reasonable evolution of food inspection in the US and worldwide.

But HACCP is not a panacea. One has to worry when a great number of people start debating and supporting any single subject. It may be analogous to the story of the "dot.coms" . . . no program or project can measure up to its sometimes-inflated expectations. Yet HACCP has achieved its objectives and will continue to provide the basis for the next evolutions for food inspection. The tool has made inspectors, manufacturers and consumer groups think about the food supply chain with its strengths and its inherent and inevitable occasional weaknesses.

The optimal food safety control methodology is not one tool, but machinery of multiples working in harmony. In the end, we come face to face with the one aspect most difficult to fully control in the equation, that's people. Tools, like HACCP, can be placed in people's hands; but their effective use will ultimately depend on how well we prepare the user for the tasks. Our effectiveness in the future will depend on how we evolve the HACCP programs initiated three decades ago to fit the environment of the future, and how well we are able to deliver cultures that support the continuous manufacture of safe food.

References

- Government Accounting Office. (1992). Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply. Washington, DC: GAO/RCED-92-152.
- Machiavelli, (1998). *The Prince*. Chicago: University of Chicago Press.
- Pierson, M. D., & Corlett, D. A. (Eds.). (1992). *HACCP: Principles and Applications*. New York: Chapman & Hall.
- Silverman, R. (2000). *Personal Communication*.
- Stevenson, K. E., & Bernard, D. T. (Eds.). (1999). *HACCP: A systematic approach to food safety*. Washington, DC: The Food Processors Institute.
- Subcommittee on Microbiological Criteria for Foods and Food Ingredients. (1985). *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*. Washington, DC: National Academy Press.