



HACCP and transparency

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Abstract

Twenty years after its first publication in the US, the HACCP system of food safety approached its current pinnacle of success in 1992 with the virtually simultaneous publication of HACCP principles and guidelines for application documents by the NACMCF and the CAC/CFH. Since then, the necessary foundation of prerequisite programs has been elaborated. Both HACCP documents were refined in 1997. All of these developments were entirely transparent. In recent years, the US regulatory agencies have promulgated three major HACCP rules for specific segments of the industry: meat and poultry products (1996), fish and fishery products (1997), and juices (2001). These specific HACCP rules, rather than maintaining the transparency of the global HACCP documents, have clouded the waters. A somewhat similar development can be noted in the EU's application of its precautionary principle. HACCP cannot provide greater transparency in the food supply chain in the context of this type of opaque regulatory environment. Rather, greater transparency, and improved public health protection, must be realized through the development of voluntary science based systems, especially involving the food processing industry, where the very idea of HACCP was conceived and implemented.

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1. Introduction

The Organizing Committee of this Forum asked us to consider the following question: “HACCP has evolved in various ways around the world from voluntary science based systems to mandatory legislation based systems. Can HACCP help provide greater transparency in the food supply chain?” The nature of the question seems to imply that there has been a contemporaneous evolution of “science based” and “legislation based” HACCP systems. This has not been the case. The proposition that I will defend in this presentation is that transparent science based systems have been superseded by opaque legislation based systems. Hence the simple answer to the above question is, “No, HACCP cannot provide greater transparency in the food supply chain when it is the subject of opaque legislation based systems”.

How are the terms “transparent” and “opaque” defined? Obviously, in the context of this Forum, we are not interested in the primary definitions of these terms, which refer to the physical transmission of light. The

secondary definitions are more useful to us. The secondary definition of “transparent” is: free from pretense or deceit, easily detected or seen through, or, readily understood. Hence, a transparent system or proposition is frank, obvious, and clear. The secondary definition of “opaque” is: obscurity of sense, or mentally obtuse. Hence, an opaque system or proposition is unintelligible, or hidden. One might think, a priori, that federal governments would strive to develop HACCP regulations and other food safety rules that were transparent. In harboring such a thought, one would be mistaken.

2. Evolution of global food safety system

The processes by which the current global food safety system and HACCP system evolved were contemporaneous and entirely transparent. The current global food safety system (Table 1), under the auspices of the United Nations, began in 1945 with the organization of the Food and Agriculture Organization. The General Agreement on Tariffs and Trade (GATT), concluded in 1947, included provisions for countries to apply measures necessary to protect human, animal, or plant life or health. Several GATT stipulations were that

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Table 1
Evolution of the global food safety system under the United Nations

1945	Food and Agriculture Organization (FAO)
1947	General Agreement on Tariffs and Trade (GATT)
1948	World Health Organization (WHO)
1963	FAO/WHO Codex Alimentarius Commission (CAC)
1994	Agreement on Application of Sanitary and Phytosanitary Measures (SPS)
1995	World Trade Organization (WTO)
1997	Codex Document on HACCP principles and application

Table 2
HACCP principles, 1972

1	Conduct hazard analysis
2	Determine critical control points
3	Establish monitoring procedures

measures adopted by an individual country must not unjustifiably discriminate between countries where similar conditions prevail, and must not act as disguised restrictions on international trade.

In 1963, the FAO/WHO Codex Alimentarius Commission (CAC) was formed both to protect the health of consumers, and to ensure fair practices in world trade. Preceding by one year the formation of the World Trade Organization (WTO), the 1994 Sanitary and Phytosanitary Agreement (SPS) has “transparency” as its most important underlying concept. Some of its particular requirements are that trading partners share information, that there be a notification before regulatory enactment, that partners have an opportunity to comment, and that there be well organized procedures and independent, objective, and transparent risk assessments.

Similarly, the early HACCP system (Proceedings of the Conference on Food Protection, 1971) was entirely transparent. In 1972, The Pillsbury Company in the US began the application of its HACCP concept to the manufacture of its consumer food products. This primordial HACCP system consisted of three principles (Table 2).

3. Emergence of modern HACCP system

In the years following Pillsbury’s first published description and applications, the HACCP system began to spread through the food industry as many companies recognized the obvious benefits of a proactive, preventive system of food safety. The US National Academy of Sciences (NAS, 1985) recognized this trend and recommended that the US food regulatory agencies change from an inspection mode (based upon infrequent plant inspections using only subjective organoleptic tools), to an audit mode (based upon a review of continuous HACCP records including verification records

Table 3
HACCP principles, 1997

1	Conduct hazard analysis
2	Determine critical control points
3	Establish critical limits
4	Establish monitoring procedures
5	Establish corrective actions
6	Establish verification procedures
7	Establish record keeping procedures

typically based on objective measures). The NAS recommendation led to the formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in 1988. The earliest projects of the NACMCF included the development of HACCP documents that described HACCP principles and guidelines for implementation.

Nearly paralleling the work of the NACMCF, the CAC Committee on Food Hygiene (CAC/CFH) began work on a HACCP document. The United States serves as the permanent chair of the CAC/CFH. Therefore, it was convenient for the two committees to collaborate to some extent in order to harmonize their HACCP documents, which resulted in the publication of nearly identical documents in 1997 (CAC, 1997; NACMCF, 1998). The modern HACCP system is built upon seven principles (Table 3). The seventh principle, establishment of record keeping procedures, secures the documentation that is necessary for review by auditors. The HACCP system and the numerous supporting records provide a completely transparent system for food safety assurance. The essence of the HACCP system is that significant identified hazards must be controlled at a critical control point. As I shall describe below, these practices of transparency and effective control measures have often been lost in the development of national food safety regulations that are promulgated as “HACCP” regulations.

4. Opacity in the US HACCP regulations

It was my privilege to have participated in the International Symposium on Food Safety and Food Trade Rules in Nanchang, Jiang-xi, China, in November 2002. After several presentations on food safety rules had been given, one of the Chinese participants asked whether the United States had any “HACCP rules” that could be used as a model for the development of Chinese food safety rules. To my considerable embarrassment, I had to confess that none of the recent HACCP regulations was true to the principles of HACCP as described by Codex and NACMCF, and none of them was transparent. In fact, the recent US HACCP rules could better be described as “opaque”.

This was a very sad realization, because earlier non-HACCP regulations developed and applied in the US were remarkably transparent. Most notable among these were the Pasteurized Milk Ordinance, first published in 1923 (PMO, 1997), and the canned foods regulations, first published in 1973 (CFR, 2002). Given the 50-year span between the promulgation of these regulations, it is one of my fleeting hopes to live until 2023, when another remarkably transparent food safety regulation might be promulgated in the US.

As evident in the three HACCP regulations discussed here, some reasons for their opacity lie in a rule-making process that is not very transparent; in the regulators' ignorance of HACCP principles and implementation, whereby prerequisite programs are confused with CCPs; and by inappropriate uses of statistics, in the name of science.

5. Meat and poultry HACCP

The Pathogen Reduction/HACCP rule for the production of meat and poultry products (CFR, 1996) received minor public input when it was discussed at an NACMCF meeting in 1994. No further public meetings were held, as USDA developed its "Megareg" without the hindrance of public scrutiny. Although public comment was accepted after the initial publication of the proposed rule, no substantive changes or improvements were made to the final rule as a result of this public comment.

In the background to this rule, the USDA recognized that the safety of meat and poultry products needed to be provided by a "Farm to Table" application of control measures. However, in a seeming disconnect from this recognition of reality, this rule applies only to slaughter/packing and further processing plants. Live animals enter one end of the slaughter plant, raw products exit the other end. No conventional critical control points (e.g., cooking) can be applied in the slaughter plant. The fundamental control of the safety of raw meat and poultry products must be implemented farther down the Farm to Table chain where definitive control measures such as cooking or irradiation can be applied and managed.

Salmonella performance standards are a hallmark of this rule. In an analogy related to the physical definition of transparency, pathogen performance standards are the black holes of food safety—all of the light is sucked out of a system and it never returns. That's what seems to have happened with this rule. Based on 1993–95 surveys of the incidence of *Salmonella* in several species of animal carcasses, and raw ground meat products, the agency established sampling plans and acceptance criteria that were different by specie and even by class within specie that must be met by each packing plant.

These criteria also had to be met even by further processing plants who only received raw materials that had been previously USDA inspected and passed prior to purchase. If the criteria were not met, the HACCP plan at a non-conforming plant would be deemed a failure. In the case of raw ground beef, for example, an agency inspector would collect one product sample for each of 53 consecutive production days. If five or fewer of the 53 samples were found to be *Salmonella*-positive, the packing or grinding plant's ground beef production was considered to be safe, and its HACCP plan was deemed acceptable. If more than five of the 53 samples were found to be *Salmonella*-positive, the plant's HACCP plan was deemed to be a failure, incapable of assuring the safety of its ground beef production.

However, failure to conform with the agency's criteria in a single round of product sampling did not mean that action would be taken against the product or against the packing plant. Rather, according to this rule, the plant would be granted an indeterminate period of time in which to review and modify its HACCP plan. Upon acceptance of the modified HACCP plan by USDA, a second round of 53 daily samples would be taken by the agency at some later time. Failure to conform to the stated criteria during the second round of sampling would re-trigger the cycle until a third round of sampling was completed. If a plant failed three consecutive rounds of *Salmonella* testing, the agency had the authority under this rule to withdraw inspection, thereby closing the packing plant. Sometimes the agency did not invoke its plant closure authority until the plant had failed four consecutive rounds of sampling.

The disconnect between the enactment and enforcement of this *Salmonella* performance standard and any direct food safety or public health protection should be obvious to even the most casual observer. How can five *Salmonella*-positive results in 53 samples be deemed to be "safe", while six positive results would be deemed to be "unsafe?" Also, if salmonella is unsafe at one level in one specie, how can it be justified that a higher incidence rate in another specie or even a different class in the same specie is acceptable and safe?

A more egregious disconnect from responsible food safety management is obvious in the lengthy periods—up to two years—necessary to complete three or four rounds of *Salmonella* testing. Several hallmarks of a valid HACCP plan are that monitoring procedures and corrective actions, insofar as possible, should be taken in real time, and should be as continuous as possible. Moreover, microbial control in meatpacking plants can be effectively verified by simple microbiological tests, such as aerobic plate counts. Under these conditions, a packing plant could rely on documented conformance to its HACCP plan as assurance that its products are safe.

The promulgation of opaque HACCP rules in the US was accompanied by another very counterproductive

and troubling development—the use of the term “science-based” by the rule-making regulators and by their supporting legislators and activists. Any discussion of deficiencies in this HACCP rule was deflected by claims that the rule was science-based. More broadly today, appeals to “science” are commonly used to discredit even the most constructive criticism of a food safety rule or policy. Any pathogen performance standard used in the context of the Pathogen Reduction/HACCP rule is not “science-based”. At best, it is a very poor and inappropriate use of statistics. The *Salmonella* performance standard is perhaps the most opaque and unfortunate flaw in the Megareg. Time and space do not permit a more detailed critique of this particular rule.

6. Seafood HACCP

The US Food and Drug Administration published its Fish and Fishery Products HACCP regulation in 1997 (CFR, 1997). This rule recites at length the HACCP principles and some of the HACCP implementation features. Its only prescriptive feature is the requirement of sanitation standard operating procedures (SSOPs), which largely echo the current good manufacturing practices extant in CFR 21, part 110. Potential and necessary controls that could be implemented during the harvesting and transportation of seafood are specifically exempted from this rule. Except for a requirement for tagging, this rule provides no new requirements for the harvesting and distribution of raw molluscan shellfish, a category that accounts for a considerable number of foodborne illnesses. Consideration of this rule developed by FDA, in conjunction with the USDA’s use of *Salmonella* performance standards in the raw meat and poultry rule; paints a picture of considerable confusion within the US food regulatory and public health agencies in their promulgation of food safety rules.

7. Juice HACCP

The Juice HACCP regulation for the production of fruit and vegetable juices (CFR, 2001) also has a number of deficiencies that disqualify it from serious consideration as a useful “HACCP” regulation. Enacted to prevent foodborne illnesses associated with the consumption of commercial raw juice products, it does not require a pasteurization step, a most obvious and logical CCP for this product category. Moreover, retail establishments that produce juice for direct sale to consumers are exempt from this regulation. It is a blessing that today’s FDA staffers were not around to write the PMO in 1923; they might have permitted retail establishments to keep cows out back to provide raw milk for consumption. While paying homage to a 5 log pathogen

reduction, the rule permits juice processors to accumulate the 5 logs at multiple process steps after the cleaning and culling of the fruits or vegetables, as long as the multiple processing steps are performed in a single production facility. This, too, undermines the conventional implementation of HACCP plans, in which control at a single process step is typically responsible for the elimination or control of a particular hazard. The final insult to our HACCP sensibilities in this rule is the permission of product testing when complete process control measures are not applied. As little as 20 ml of juice from one week’s production (up to 1000 gallons of juice), needs to be found free of *Escherichia coli* to provide assurance that the entire week’s production is safe for consumption.

Over the past sixty years we have learned a hard lesson many times over—product testing is not an effective means to assure food safety. This lesson is particularly true when the defect of concern occurs at a low incidence (<1%), a level typical of foodborne pathogens that are present on those relatively rare occasions when a lot of food is actually contaminated with a pathogen. The failure of product sampling to assure food safety is the very reason that the HACCP system of food safety was developed in the first place. It is tantamount to sacrilege to test 20 ml of juice per week and call it HACCP.

8. Translucency in the EU precautionary principle

Fortunately, perhaps, I have neither the time nor the expertise to critique food safety rules in other countries. However, it could be considered unfair to harshly judge the US HACCP rules, when HACCP rules in other countries could be similarly non-scientific and counter-productive. Therefore, I will make a few comments about the European Union’s “precautionary principle”, a recent development that may be a global harbinger of continued confusion in food safety regulations. From my vantage point, the precautionary principle is not entirely opaque in ways that US HACCP rules are, so I will refer to it as “translucent”, for the present.

The precautionary principle was adopted to allow public health authorities to make decisions regarding public health protection in the absence of complete scientific information. Ideally, the precautionary principle can be invoked when reasonable grounds of an unacceptable public health risk exist, and, when available data are insufficient for a comprehensive risk assessment. Under such conditions, measures can be taken to protect the public health, however, such measures are *provisional* until more complete information is available.

Citing public concern about food safety created by the bovine spongiform encephalopathy (BSE) epidemic in Europe, and by a major incident of dioxin contami-

nation in poultry feed that affected the food supply; the EU Commission announced in 2002 that it would ban all remaining uses of antibiotic growth promoters (AGPs) in animal feed by 2006. Other than public skepticism and fear, there is no connection between BSE, dioxin, and AGPs. Moreover, the remaining AGPs in use in the EU are all ionophores, which function as coccidiostats in animals, and have no use in human therapy. While there is no scientific need to have a complete AGP ban, the EU decision will likely have an undesirable ripple effect for animal production in all regions of the world that use AGPs judiciously and trade with the EU.

Similar EU restrictions on growth hormones, foods produced from genetically enhanced crops, and the presence of acrylamides in food are based on public perception and fear rather than upon scientific evidence. Which raises the question in my mind: are the Europeans using a “precautionary principle”, or a “paranoia principle”?

9. Conclusion

Let us return to the original question under consideration: “HACCP has evolved in various ways around the world, varying from voluntary science based systems to mandatory legislation based systems. Can HACCP help provide greater transparency in the food supply chain”?

Clearly, the legislation based systems critiqued above are not only *not* providing greater transparency, but they are actually creating greater opacity in our attempts to improve food safety management efforts. However, we *must* be able to answer this question in the following way: “Yes, HACCP can provide greater transparency”, if we are to make progress in our ability to effectively manage food safety programs and to better protect the public health. We should remember that HACCP began as a voluntary science based system in the food industry. The food industry today remains, by far, the greatest repository of food safety management and food science experience and expertise, and it has the ultimate responsibility for the safe production of foods. Rather than meekly accepting the consequences of non-

scientific food safety rules, the food industry should use its intellectual assets to assert its leadership, as it did with the conception and advancement of HACCP, in order to formulate effective science based food safety rules. It is, obviously, difficult for regulators working in isolation to create science based rules. Similarly, effective food safety rules can never be developed by food safety professionals acting unilaterally. Rather, food safety professionals in the food industry, academia, and regulatory agencies must collaborate with other concerned stakeholders to improve this situation by creating effective science based food safety rules and policies. Such an undertaking will not be easy. It will likely be contentious. But, such collaboration is necessary in order for all stakeholders to use existing resources efficiently in order to better protect the public health.

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