

Food Safety Issues in the International Marketplace

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Introduction

We are in the middle of a food safety revolution, a revolution that likely began in the U.S. and has spread worldwide in the past five years. While changes in food safety regulations have been ongoing worldwide for at least two decades, and while most of the major food producing countries in the world have been actively addressing food safety issues and making changes in their food safety policies in order to better protect the public's health, the events that occurred in January and February of 1993 triggered the revolution that we are experiencing today. As we all know, in 1993, the northwest part of the U.S. experienced the largest outbreak of *E. coli* O157:H7 in its history. Three children died in that year and over 600 people became ill. Other events were occurring at the same time—a new President, a new Secretary of Agriculture, and much stronger consumer advocate access to the White House, the Department of Agriculture and Congress. There is no doubt that the death of three children in 1993, coupled with the aforementioned events, triggered the food safety revolution. Other events, such as BSE in Great Britain and Europe; the *E. coli* O157:H7 outbreak in Japan (largest in the history of the world); the *E. coli* O157:H7 outbreak in Scotland, etc., have all added fuel to the revolution. What is the impact of the events over the past five years on the food producing and exporting countries of the world? Are food regulatory policies being driven by good science? Do we have sufficient science? Are we dealing more with perceptions than realities? What does the future hold?

Results of the Revolution

The events over the past five years have produced a number of actions and policy changes. Many of the products of change are highly significant and will have a dramatic impact on the future of food industries worldwide. A few of these changes are worthy of discussion at this stage.

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Former Secretary of Agriculture, Michael Espy, announced in May of 1993 that USDA intended to develop and implement policies that would mandate HACCP for all federal and state inspected meat and poultry plants. With that announcement, it was obvious that the industry would have to begin to prepare to train itself in an effective and standardized manner. With that realization, a group of individuals representing over 20 meat and poultry associations met at Texas A&M University in March of 1994 to form the *International Meat and Poultry HACCP Alliance*.

The International Meat and Poultry HACCP Alliance was a proactive step to assist the meat and poultry industry in preparing for mandatory HACCP. The founders of the HACCP Alliance recognized the need to standardize HACCP training efforts, develop a uniform position on implementing HACCP, and work cooperatively with USDA's Food Safety and Inspection Service (FSIS). Therefore, the HACCP Alliance has devoted the past four years to these activities. During this time, five standardized curricula have been developed, 26 training programs have been accredited, and over 100 individuals have been approved as lead instructors. The HACCP Alliance members have also striven to encourage the adoption of HACCP throughout the meat and poultry industry and foster better communication and cooperation with USDA's FSIS and other governmental agencies worldwide.

The goals of the International HACCP Alliance (name was changed at its last Board meeting) are listed below:

- to provide standardized curricula and accreditation for HACCP/food safety courses;
- to be recognized as the worldwide HACCP authority;
- to facilitate the standardization of support systems for HACCP;
- to foster understanding and cooperation among industry, academia, consumers and government regarding HACCP and food safety.

The membership of the Alliance is impressive and continues to grow. The members are made up of industry associations (26), educational foundations (3), professional associations (12), third party service providers (22), universities (42) and government agencies (23). The executive director of the International HACCP Alliance is Dr. Kerri Harris. She can be reached at 120 Rosenthal, Texas A&M University, College Station, TX 77843.

USDA Mega Reg

USDA's Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) System's final rule (July 1996) is the largest and most significant policy change in the history of meat and poultry inspection. Industry calls it the "Mega Reg" because of its size and significance. To illustrate the significance of the Mega Reg, President Clinton announced the final rule in the Oval Office in July of 1996. USDA's final rule contains three key parts:

1. Mandatory sanitation standard operating procedures
2. Mandatory *Salmonella* performance standards (collected by USDA) and generic *E. coli* guidelines (collected by company)
3. Mandatory HACCP

Sanitation SOPs went into effect in January of 1996. Mandatory HACCP for large plants (>500 employees) went into effect in January of 1997. Plants with 10-500 employees must have HACCP systems in place by January 1999. All remaining meat and poultry plants must have their systems in place by year 2000.

How is the Mega Reg and its mandatory requirements working to date? Is the industry adequately preparing itself to implement the USDA requirements? Is USDA preparing itself to provide oversight to an industry implementing HACCP?

Is Industry Ready?

It is believed that the 312 plants in the U.S. that went on the mandatory HACCP program in January of this year had HACCP systems in place for a number of years. Many believe that the greatest expertise in HACCP resides within the private sector. In addition, with the HACCP Alliance and its accredited courses and approved lead instructors, hundreds of industry personnel have received accredited training over the past four years. It is also believed that many of the small plants scheduled to go on line in January of 1999 have HACCP systems in place and will be prepared to meet USDA requirements on or before 1999. While many of the 3,000 plus companies that will be going on line next year are prepared, too many are not. It is feared that the USDA mandatory requirements for these companies will have a very negative impact because of the cost of implementing HACCP and because they are not prepared. Companies that have to be on line in 1999 should have their total food safety programs in place by the fall of 1998. It is believed that too many of the intermediate to small companies are not taking the Mega Reg seriously enough. Meat and poultry extension specialists and other university faculty have been devoting a tremendous amount of time to prepare companies in their state. This activity must continue or even be accelerated if we are to avoid a disaster in 1999. In addition, USDA should be encouraged to enhance their support of these activities within the states, as well as its own activities.

Is USDA Ready to Provide Oversight?

Secretary Glickman and FSIS Administrator Tom Billy say yes, while the industry says no. The experience to date with the 312 companies coming on line this year has not been positive. The specifics are much too involved to go into in this text, but it appears that:

1. FSIS personnel do not fully understand their oversight role in regard to HACCP.
2. FSIS personnel have not been adequately trained in the principles of HACCP. While most of the meat and poultry industry has gone through a three-day Alliance accredited HACCP course, USDA inspectors receive most of their training on how to regulate HACCP. Industry believes that one should know how to develop and implement HACCP plans before you can provide oversight as to whether or not it has been implemented effectively.
3. Many believe that the "command and control" approach to meat and poultry inspection should decrease under a HACCP system, but, in actuality, it has increased.
4. The USDA meat inspectors union does not support HACCP and has sued USDA to prevent a move away from continuous inspector oversight. This is obviously a job-related issue and not a food safety issue.

Project II-Australia

Most believe the following regarding HACCP:

1. That it should be developed and implemented by industry.
2. That government regulators should provide qualified and effective oversight over the implementation of these plans.
3. That daily (continuous) inspector presence is not necessary and counter productive.

Moving away from a daily or continuous inspection presence is a very sensitive issue within many countries, especially the U.S. While many believe that it is the correct path to take, it is not the easy path for obvious reasons. The industry and AQIS in Australia decided to take that path some years ago. They took the unique approach of trying to use "science" to justify a policy change. The first step was to conduct a pilot of the new inspection model in three domestic meat plants. In this model, companies were required to develop a safety system based on HACCP that included on-line sorting normally done by government inspectors. The companies' quality systems were audited and monitored by government inspectors to ensure food safety standards set by government were maintained by each company. This concept shifted the responsibility for safety to the company. AQIS collected a significant amount of data before, during and at the end of the tests. Bottom-line, the new approach produced a safer product. This result is believed to have occurred because the plant man-

agement and personnel knew that the responsibility for product safety was theirs, and they knew that the consequences for failure were severe.

Australia was so pleased with the results from its domestic pilots that it was implemented nationwide. Since Australia exports a significant amount of its meat, the next step was to test this concept in its export plants. AQIS approached USDA in 1997 requesting USDA that it allow meat from plants going through this type of test to be exported to the U.S. USDA elected to seek comments from the public, even though it was unnecessary. As expected, the inspectors' union and the consumer advocate groups said no, while the scientific community and the private sector said yes, an excellent example of public health policy not being made by science. AQIS and USDA are still working on this issue, and hopefully some compromise will be reached. AQIS has submitted a modified pilot proposal to FSIS called *Meat Safety Enhancement Program (MSEP)* to try to address FSIS concerns about the level of government inspector oversight in the original Project 2 proposal. MSEP is the basis of continuing discussions between FSIS and AQIS.

Bacterial Testing Craze

With the Mega Reg, the *E. coli* O157:H7 outbreaks, bacterial performance standards, etc., we find ourselves in a major microbial testing mode. Sampling for microbiological organisms has a strong role in total food safety programs. Testing is effective for measuring the effectiveness of sanitation, interventions, etc. Testing is effective for trend analysis of pathogens and change over time. Testing is not as effective in "test and hold" or "accept/reject" programs. The test and hold philosophy is what is taking hold in our industry today. This is a dangerous trend because:

1. Bacteria are not uniformly distributed in food; thus, very large samples are necessary to have any statistical validity. Large numbers of samples are not justified, and that is the reason that HACCP was developed over 30 years ago. It was realized that "test and hold" programs were not scientifically valid and that it was impossible to "test" safety into food.
2. Because the sample sizes taken by USDA and industry are so, by necessity, small, a positive or negative result has no scientific meaning in regard to food safety. A negative result does not mean that the product contains no pathogens and is safe to handle differently (rare hamburger) nor does a positive result mean that the entire lot is unsafe.

It is time for the regulators, the scientific community and the industry to come together to develop a science-based set of standardized protocols for microbial testing in and around food safety and HACCP programs. If this is not addressed very soon, the testing mania will be totally out of control, and the concept of prevention and HACCP will

become secondary. It is time to put "science" back in and politics out of good public health policy making.

Trace-Back and/or Source Verification

Animal I.D. or trace-back is here to stay. Those in the food industry who cannot embrace the concept of trace-back will have a difficult time in the coming years. In the very near future, we will have to have the capability to trace-back from the retail cut in the marketplace back to the farm. In the intermediate future, we will have to have the capability to trace from the retail cut to the parents of the animal that produced that product. Trace-back from a ground product will be important but much more difficult. Short-term, trace-back will be necessary from the marketplace to the company that produced the ground product. There is also an increasing trend in the U.S. and other countries to form alliances where total animal history is known and the product is produced in totally closed systems. These types of alliances or partnerships will accelerate the trace-back activity. The drivers for trace-back will be a combination of government and customers. In some countries, the primary driver will be the government, while in others, it will be the customer (either actual consumer or immediate provider to the consumer).

Drivers for Animal I.D. or Trace-back Include:

Food Safety: The primary driver for implementation of individual animal identification systems is food safety. In many countries—especially EU member nations—consumer confidence in beef is extremely low. Trace-back capability is viewed as a means of recapturing that confidence.

Disease Control and Eradication: A national individual animal identification system would greatly facilitate disease control and eradication by providing more accurate information about the origin of cattle and the ability to identify other cattle with which a diseased animal has had contact.

Quality And Consistency: Information exchange is a common deficiency throughout the meat industry. The implementation of individual animal identification systems, coupled with new technology, is the tool needed to fill this void.

Ability to Compete in Global Markets: Individual animal identification will likely replace the "Hormone Ban" as a means to limit access to the European Market. Under the GATT agreement, a requirement that U.S. producers provide for similar individual animal identification would likely be required.

Animal I.D. by Selected Countries:

European Union (EU): Of the 13-member nations of the EU, 12 currently have some form of national identification system in place. In almost all instances, these systems are mandatory and utilize bar-coded eartags. A three-year research project is underway in the EU to test electronic systems (rumen bolus, external, and implanted). The primary purposes of implementing mandatory individual animal identification systems among EU member nations is to re-establish consumer confidence in beef following the BSE crisis. Full implementation is set for the year 2000. The system will require all calves to be identified within 30 days of birth and a "passport" issued for that animal by a government authority no later than 14 days after notification of birth. This passport must accompany the cattle and, in the case of death, submitted to the authorities within seven days after death. The entire EU system is estimated to cost \$3 billion (in U.S. dollars).

Netherlands. Since 1991, all newborn calves must be identified by two eartags (premise and cattle number) within three days of birth. Information (calf's eartag number, dam's number, and sex) is supplied via phone by the producer. To market cattle, both the buyer and seller must be registered with the appropriate regulatory authority and the same notified of each buy/sell transaction. The system allows for tracking of animals and individual cuts derived from the same to the retail level. During 1994, it was estimated that 10 million notifications (birth registrations, marketings, death, etc.) were processed by the central database server. Estimated operational costs of the database in 1994 was \$75 per animal (in U.S. dollars).

France: The French identification system was officially implemented June 1, 1997. At birth, the owner is required to eartag all calves with a premise tag. An official government eartag must be applied no later than four months of age, with application of the "official" tag conducted by a governmental official. The government identification number is then entered in a central database and a "passport" issued. Similar to the Dutch system, when an animal changes ownership, both the buyer and seller must notify the appropriate authorities. At the retail counter, the following information is provided: breed, age, sex and slaughter date. The cost of mandatory individual animal identification to the owner (tag and data registration) is estimated between \$3.50 and \$4.50 per head (U.S. dollars).

Australia/New Zealand: Australia and New Zealand are currently conducting a "National Cattle ID Trial" on the use of a dual tagging system for adoption as a voluntary national identification system. This three-year research project was initiated in January of 1997 and will be conducted in several phases. An additional component of the research is to determine the most suitable bar code system

to use on tags and to standardize the same. Two dimensional bar codes will be evaluated as they offer additional information with less space requirements as existing UPC bar codes.

Canada: The province of Quebec currently has a mandatory animal identification system that uses bar-coded eartags. Similarly, Beef Improvement Ontario (BIO) is currently utilizing bar-coded eartags to provide information feedback to producers using its services. The Canadian Cattlemen's Association has appointed a working group to study the feasibility of implementing a national identification program. This group is charged with developing a business plan for administration of the system, using its Beef Grading Agency as a model for the management structure of a national identification system. To date, it intends to utilize a "central registry" for data accumulation/storage, with "service organizations" (breed associations, provincial associations, and the existing dairy industry identification system) serving the role of clearing houses for identification system distribution and decentralized data accumulation. The Canadian system is being designed as a voluntary program with initial efforts focused on trace-back for animal health purposes. Initial indications suggest it is leaning toward a visual eartag system (either curl-tags, or small button-shaped tags) that will require manual reading at the packing plant. To maintain confidentiality of individual producer information, access to the database will be limited.

United States: Development of new marketing initiatives/strategies are increasingly incorporating "Animal Source Verification" as a specification for participation. The Nebraska Corn-Fed Beef program will utilize eartags that incorporate a logo, premise ranch I.D. number, and a unique animal number to identify cattle in the program.

California Dairy Cattle and Veal Calf Identification Law—Currently a premise backtag (similar to the MCI backtag) is applied by dairy and veal producers in the California for trace-back purposes. Premise tags must be applied prior to sale/slaughter. The primary goal of the program is to address violative drug residues found in dairy cattle.

Commercial Application—At present, there are numerous commercial systems that are being applied in the U.S. The majority of these systems are utilizing electronic identification as a means of providing cattle producers and feeders with data (cattle performance and carcass information) captured through this technology.

NCBA Policy—Identification

1. Supports animal identification for production evaluation, disease control, and trace-back capability
2. Supports development of an industry driven, voluntary, universal electronic identification system

3. Supports development of new identification systems, including electronic systems—vigorously opposes efforts to accomplish a mandatory national identification system

Are We Making Good Decisions with Good Science?

Making policy with good science or being a science-based organization are phrases that we hear often. Are they just words? Are we using the science we have available to make good policy decisions or advance the public health cause? Do we have enough science? If one looks at the past five years in the regulatory community, one would have to say that “science” is taking a back seat to politics as policies and regulations are developed. If true risk analysis to public health were used to determine how we spend our inspection dollars, there is no question that we would have a different approach to food safety worldwide. The EU hormone ban, the ban on bone-in beef in Great Britain, and *E. coli* O157:H7 as an adulterant in the U.S. are just a few examples.

It would be great if we could say tomorrow that all future regulatory or policy decisions would have to be supported by a strong and scientific risk analysis and strong published, peer reviewed scientific data. Policy that would be influenced by special interest groups which had no bearing on public health protection would not be tolerated. Given the reality of politics and the reality of the environment that we live in today, the aforementioned is not likely to happen. Perhaps we should strive to obtain some balance in policy making between politics and science. Let’s set a goal to move from the current less-than-20% focus on science to at least 50%.

In order to accomplish these goals, a number of things have to happen:

1. We need to make certain that we have good science. We need to be spending the right amount of resources on the highest priorities. The meat and poultry industries, the taxpayers, etc., all devote tremendous resources to the development of the science necessary to make food safer. Unfortunately, the resources devoted to the “science” of food safety is not sufficient. Even though Congress and the President have devoted millions of new dollars in their food safety initiatives over the past two years, these dollars are just not enough. In addition, most of these dollars are being devoted to new inspectors or food-borne illness surveillance. These are important focus areas, but these activities do little to answer the scientific questions that must be answered. For example, the Beef Industry Food Safety Council recently identified over \$50 million in research questions that need addressing—this is above and beyond what is currently being devoted to beef safety. The pork and poultry industries have similar priorities.

2. The private sector must work together to focus its energy and priorities in a coordinated effort to deal with policy. Neither Congress nor the Executive Branch will listen to a divided industry. The same could be said for industries throughout the world—divided you fall, etc.
3. The scientific community must speak out on key issues. Too often, the scientific community stays silent when policies are being developed and implemented that are based on bad science or no science at all.

Conclusions

Vision: The food safety system of tomorrow will be based on the principles of risk reduction, prevention, and risk analysis. The food safety system of tomorrow will apply HACCP principles and risk analysis procedures to all levels of meat and poultry production from the farm to the consumer’s table. These principles and procedures will be applied by the private sector with effective third-party oversight.

Components of the Future System Include:

- Resources will be allocated based on risk reduction from the farm to the table.
- Continuous inspection of carcasses and birds will be reduced or based on risk to public health. Focus will shift to an industry using HACCP with effective third-party oversight.
- Ante-mortem inspection and post-mortem pathology will remain under the oversight of a third-party veterinarian.
- Continuous inspection at processing facilities will be based on risk and plant performance using HACCP. All oversight (inspection) tasks will be based on effective risk analysis and will use the PBIS (Performance Based Inspection System) to assign daily tasks from slaughter to food service and retail.
- Inspection resources will be used at slaughter, processing, transportation, food service, and retail in a HACCP oversight mode. As the science becomes available, focus would be expanded to the farm.
- National microbial pathogen marketplace baselines will be used on raw and cooked products to evaluate the effectiveness of the industry as a whole in regard to improvements.
- Third-party oversight will be provided by personnel who have been adequately trained in the biological and physical sciences. The entry level and training requirements for program personnel will increase significantly as they become trained and accredited to evaluate an industry using HACCP.

Needs from Congress:

- Combine all federal food safety programs into one new agency.
- Evaluate the three acts—meat, poultry and food—to eliminate differences, standardize risk-based approaches, intensity of inspection, etc. Combine three acts into one act.
- Establish oversight responsibility for enactment and revision of food safety regulatory activities. Oversight group should consist of scientists who have appropriate credentials.
- Give the new regulatory agency the authority to base assignment of resources on risk (move away from continuous inspection).
- Ask the regulatory agency to propose a plan for effectively evaluating science used to decide policy.