


## Managing Food Safety Practices from Farm to Table: Workshop Summary

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# Managing Food Safety Practices

## **F R O M F A R M T O T A B L E**

Workshop Summary

Leslie Pray and Ann Yaktine, *Rapporteurs*

Food Forum

Food and Nutrition Board

**INSTITUTE OF MEDICINE**  
*OF THE NATIONAL ACADEMIES*

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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*“Knowing is not enough; we must apply.  
Willing is not enough; we must do.”*

—Goethe



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FOOD SAFETY: CHANGING MARKET FORCES,  
EMERGING SAFETY ISSUES, AND ECONOMIC IMPACT<sup>1</sup>

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## Independent Report Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

**Larry R. Beuchat**, Center for Food Safety, University of Georgia  
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**Jennifer Weber**, American Dietetic Association

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by **Eileen T. Kennedy**, Friedman School of Nutrition Science and Policy, Tufts University. Appointed by the Institute of Medicine, she was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authors and the institution.





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## Overview

U.S. policy makers are addressing the issue of food safety in a very serious way and unlike ever before in the history of this Nation. The science of food safety has advanced tremendously over these past 10-15 years. Several new coalitions have formed with the goal of educating Congress about food safety, and the 110th Congress is considering several food safety-related bills. As recent events attest, from melamine-tainted milk products from China to *E. coli* O157:H7-contaminated spinach from California, new and unforeseen food safety risks are continuing to emerge, impacting countries and consumers worldwide. Given recent recognition of the serious nature of the issue of food safety at the national level, not just in Congress but also in the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA), both federal agencies charged with ensuring the safety of the food supply, and elsewhere, stakeholders are asking: What can the U.S. government do to facilitate efforts to improve food safety, either through policy or perhaps even legal mandate? In response to concerns among food producers, regulators, consumers, and other stakeholders, the Institute of Medicine's (IOM's) Food Forum met in Washington, DC, on September 9, 2008, to address this question. Specifically, the meeting explored ways to manage food safety practices from the supply chain to the marketplace; including ways to develop systematic, risk-based strategies for prevention of microbial contamination in foods, particularly produce, thermally processed foods, and meats. The workshop also served as a forum for experts on various disciplines to discuss approaches, technologies, and institutional strategies to manage food safety risks in a global market.

The impetus for this workshop developed from Food Forum discus-

sions on recent trends in outbreaks and ways to predict their occurrence. Initially, Forum members anticipated an examination of systems and strategies that allow, or would allow, for making such predictions. The dialogue rapidly shifted, however, from questions about prediction to questions about prevention. Finally, Forum members conceived of a workshop where government, industry, consumer, and academic interests would meet to consider ways to develop systematic, risk-based strategies for prevention of microbial contamination in foods, particularly produce, thermally processed foods, and meats. Specifically, the workshop was designed to serve as a forum for discussion on approaches, technologies, and institutional strategies to manage food safety practices in a global marketplace.

After a brief introduction by Food Forum Chair Michael Doyle and Food Forum member Ned Groth and keynote remarks from Michael Taylor, 11 experts from many fields gave formal presentations on lessons learned from recent outbreaks in various food products; strategic approaches to outbreak control; and future solutions to outbreaks in produce, thermally processed foods, and meats. A panel discussion and comments and questions from members of the audience broadened perspectives and added to the dialogue. This report is a summary of the workshop presentations and discussions. The meeting transcripts and presentations served as the basis for the summary. The agenda for the workshop appears in Appendix A; Appendix B lists the workshop participants; Appendix C contains the biographical sketches for the presenters, moderators, and panelists; and Appendix D lists acronyms and abbreviations used throughout the workshop.

The reader should be aware that the material presented here expresses the views and opinions of individuals participating in the workshop either as presenters, panelists, or audience members, and not the deliberations or conclusions of a formally constituted IOM committee. The purpose of the workshop was not to come to consensus on any single issue. In fact, while some speakers and participants agreed on some issues, a notable feature of the day's discussion was the wide divergence in opinion on many issues. Nor was the goal to comprehensively address all pertinent food safety issues. These proceedings summarize only the statements of workshop participants and are not intended to be an exhaustive exploration of the subject matter.

# 1

## Introduction

### SETTING THE CONTEXT

#### What Characterizes an Effective Preventive Food Safety System?

In his workshop introductory remarks, Ned Groth<sup>1</sup> explained that, while planning this workshop, Forum members developed a set of key criteria for an effective preventive food safety strategy or system. A protective food safety system should be:

- systematic (i.e., from farm to table);
- risk-based (i.e., with set priorities and established risk management practices);
- transparent and participatory;
- cost-effective; and
- minimally disruptive of trade (which is an obligation of all countries regardless, as per the SPS Agreement<sup>2</sup>).

These criteria served as a framework for the day's discussion. The first three criteria in particular figured prominently during the course of the workshop, with an emphasis on:

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<sup>1</sup> Edward Groth III, PhD, is a Consultant with Groth Consulting Services, Pelham, NY.

<sup>2</sup> The SPS Agreement is the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures, adopted in 1994, which allows members to take appropriate and scientifically based measures to protect public health as long as they do so in a manner that minimally disrupts trade.

- the need for more transparent and effective communication among all stakeholders and the need for all farm-to-table stakeholders to participate in food safety management;
- the need to consider the global scope of the farm-to-table food production process; and
- the need for science- and data-based decision making when attempting to improve the safety and lower the risks of food production.

Cost-effectiveness and the obligation to minimally disrupt trade were mentioned during the course of the workshop discussion but were not elaborated on to nearly the extent that the other criteria were.

### *Is Food Safety Solvable?*

Also in his opening remarks, Groth emphasized that progress can be achieved and that even very difficult food safety problems are solvable. As an example, he told an anecdotal story about some shipments of shrimp from Southeast Asia being refused entry into the United States and European Union (EU) a number of years ago because of the detection of unacceptable levels of chloramphenicol residue.<sup>3</sup> The refused entries had a devastating effect on shrimp export throughout Southeast Asia. Over the last five years, however, the Vietnamese shrimp industry has made a terrific comeback, despite initial problems in educating the thousands of low-tech and largely illiterate shrimp farmers about what they needed to do to correct the problem. Largely through technical assistance provided from several European countries, the Vietnamese government has developed a surveillance, monitoring and analytical capacity that simply did not exist at any level five years ago. Today, the United States and EU account for almost half of all Vietnamese shrimp exports.

A handful of other success stories were told elsewhere during the course of the day's discussion. For example, at one point during the day's discussion it was noted that many developing countries that one might not necessarily expect to have sophisticated food safety systems in place are nonetheless able to meet the very high EU import standards. It was suggested that perhaps this is because of direct working relationships between exporting and importing countries and the agencies therein.

Groth's introductory remarks were followed by Taylor's keynote address: *Institutional Roles in Risk-Based Management*. A key message of

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<sup>3</sup> Chloramphenicol is an antibiotic that is typically administered only as a last resort treatment for difficult-to-treat bacterial infections in humans. U.S. federal regulations prohibit its use in food-producing animals or animal feed products, however, due to its unpredictable effects in some human patient populations.

Taylor's talk was that food safety is as much an institutional challenge as it is a scientific, business, or regulatory challenge. The "good news" with respect to food safety, Taylor said, is that policy makers are "getting it." Food safety is on the radar screen and, in fact, Americans are at a turning point in their history with respect to having the opportunity, means, and political will to improve our food safety system. But institutional roles and responsibilities still need to be clarified, institutional capacity needs to be strengthened (so each institution can meet its responsibilities), barriers to information exchange and collaboration need to be broken down, and new mechanisms for collaboration need to be created. In short, even with the increased policy focus on food safety, far more work needs to be done in order to foster an institutionally integrated, systems-based approach to food safety. Taylor's emphasis on the institutional nature of the challenge of food safety was a major underlying theme of the remainder of the workshop presentations and discussions.

### *Organization of the Workshop and This Report*

The remainder of the workshop was organized around three major sessions:

1. *Lessons learned from recent outbreaks and other past experiences* in a range of foods (i.e., from minimally processed to highly processed) and under a range of regulatory frameworks (i.e., from reliance on good agricultural practices, or GAPs, to the use of very strict low-acid canned food regulations), as well as lessons learned from scientific research on consumer behavior. In addition to the respective roles of industry and government and the need for more transparency and collaboration between these two sectors in particular, other major topics of discussion during this session included the essential role of science in the development of safe food production systems and the need to make data-based decisions when designing such systems; the argument that testing and audits are verification, not preventive measures; and how research has shown that consumer education by itself are not a sufficient preventive measure against foodborne illness.
2. *The range of strategic approaches to improving food safety that is being considered or has already been implemented.* These approaches range from the technological (e.g., advances in molecular detection technologies) to changes in how the public and private sector can or should interact. In addition to the continued discussion on the respective roles of industry and government and the need for more collaboration between the two sectors, other major



topics of discussion during this session included the global nature of the U.S. food supply and the critically important role of risk-based supply chain management; and the reality that, while new testing technologies are becoming available, again, testing is not prevention—there is a need to better utilize the technological tools and knowledge already in place. This session ended with what was arguably the most conceptual presentation of the day: Julia Caswell’s “big picture” examination of different public–private sector combinations and strategies used elsewhere and in the U.S. and the need to consider whether this country should adopt a more comprehensive approach to food safety management rather than relying on its current reactive, risk-by-risk approach.

3. *Future steps toward improving and ensuring the safety of our food supply.* This session involved a four-person panel with representatives from industry (Cargill Inc.), a consumer advocacy group (Center for Science in the Public Interest) and two regulatory agencies (Center for Food Safety & Applied Nutrition [CFSAN]<sup>4</sup> and the Food Safety and Inspection Service [FSIS]<sup>5</sup>). Each panelist was asked to provide some perspective on what they had heard during the course of the previous sessions. The issue of the respective roles of industry and government and the need for more private–public sector cooperation and coordination again figured prominently throughout the session. The panelists offered opinions and insights into *how* this might be achieved, for example whether the formation of a single unified food safety agency could be an option. There were starkly contrasting views on the practicality and potential of such an agency, with both regulatory agency representatives strongly opposed to the notion and the consumer advocacy representative and some audience members in favor. Both regulatory agency representatives and the private industry representative briefly described some recent or pending food safety measures being implemented or planned by their respective institutions. Another major topic of discussion was the challenges that stem from the increasingly global nature of our food supply chain, such as ensuring that agricultural suppliers are adhering to good sanitary practices.

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<sup>4</sup> CFSAN is one of six product-oriented centers within the U.S. FDA. In conjunction with FDA field staff, CFSAN is responsible for promoting and protecting public health by ensuring that the U.S. food supply is safe, sanitary, wholesome, and honestly labeled and that cosmetic products are safe and properly labeled.

<sup>5</sup> The FSIS is the public health agency in the USDA responsible for ensuring that the Nation’s commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

This workshop report is organized around these three sessions, with Chapters 2, 3, and 4 summarizing the presentations and discussions of the first, second, and third sessions, respectively. A paraphrased summary of Taylor's keynote presentation follows.

### KEYNOTE ADDRESS: INSTITUTIONAL ROLES IN FOOD SAFETY RISK-BASED MANAGEMENT<sup>6</sup>

*Presenter: Michael Taylor<sup>7</sup>*

Michael Taylor began by remarking that regulators and industry often think about food safety as a scientific, business, or regulatory challenge. He argued that there is another way to think about food safety: as an institutional challenge. In fact, it is practically unavoidable to look through the institutional lens when deliberating an effective farm-to-table risk-based approach to food safety. Food safety success depends on the behaviors of many different types of institutions—for example, how institutions interact with each other and whether and how institutions are incentivized to do certain things. How institutions work well together, or not, and share data, or not, significantly impacts outbreak management success and the timeliness, or lack thereof, in resolving food safety problems.

The extent to which institutions work well together is particularly important with multi-state outbreaks, where not just the federal government but also the governments of multiple states are responding. Taylor pointed to the *Salmonella* Saintpaul outbreak,<sup>8</sup> which involved 40-plus states, as an example of the vital role that institutions play in outbreak response situations. Not only are multiple levels of government involved in these types of situations (i.e., federal, state, and local governments), but within each level there are multiple institutions:

- At the *federal government* level, there are the Centers for Disease Control and Prevention, or CDC (playing the “epi role”), and both the FDA and USDA (playing distinct regulatory roles). Together, these agencies play key roles in national coordination, traceback, and risk communication.

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<sup>6</sup> This section is a paraphrased summary of Michael Taylor's keynote address.

<sup>7</sup> Michael Taylor, JD, is a Research Professor at George Washington University, Washington, DC.

<sup>8</sup> The *Salmonella* Saintpaul outbreak began in April 2008, with the first cases reported to the CDC by the New Mexico Department of Health in May. Within weeks, the outbreak expanded to include 43 states, the District of Columbia, and Canada. By the end of August, the outbreak appeared to be over. Jalapeño and Serrano peppers grown in Mexico were identified as the main source of contamination.

- At the *state and local government* level, there are the public health labs, health departments, and food inspection agencies, all of which not only must interact with each other but also with the various federal institutions. State and local governments typically work on the frontline during outbreak responses and play critical roles in early detection.
- Added to these is the obviously central role that the private *food industry* plays, including food producers, processors, and retailers. Not only are private companies critical sources of information, they are also responsible for managing the recalls.
- Finally, there is the *public*, which includes the press as well as outbreak victims and other citizens. The latter serve as the ultimate measure of the effectiveness of any food safety system or strategy.

While certain institutions may seem to have particular primary roles (e.g., the federal government is responsible for national coordination), multiple institutions from these different sectors typically work together on most activities. For example:

- When conducting *hazard identification and analysis*, while the responsibility falls first and foremost on private industry, clearly both the federal government regulatory groups (including CDC, FDA, and USDA) and government and academic research groups play important roles as well.
- Likewise with *developing and implementing interventions*: while this is primarily an industry responsibility, the Agricultural Research Service (ARS) and other research organizations are active in this area as well.
- *Setting food safety standards* is primarily a government activity, with the FDA, USDA, and state and local agencies all involved, Codex,<sup>9</sup> the International Organization for Standardization (ISO) and other international standard-setting bodies also play a role. Increasingly, food companies and retailers are also setting food safety standards through purchase specifications and other means.
- Finally, while *verifying and enforcing compliance* has traditionally been perceived of as a government role, the private sector partici-

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<sup>9</sup> Codex is the Codex Alimentarius Commission (CAC), an intergovernmental organization jointly run by the Food and Agricultural Organization (FAO), and the World Health Organization (WHO). Codex is responsible for compiling the standards, codes of practice, guidelines, and recommendations of the Codex Alimentarius, an international set of food standards often referred to as the “Codex standards.”

pates as well (i.e., through commercial purchasers and third party auditors).

All of these various mixed responsibilities across all of these areas of food safety and risk management highlight the reality that institutions are highly interdependent in outbreak response and other food safety situations. Effective institutional interaction is critical to their success. This is true no matter what the situation is—whether it is a traceback, outbreak investigation, or prevention activity.

The reality is that there is an enormous number and diversity of institutions with widely divergent perspectives and capacities working on the same problems. This poses a tremendous challenge. Precisely because of their divergent perspectives and capacities, most institutions have a tendency to work within a particular set of traditional practices. Taylor referred to a recent examination of the food safety information infrastructure, an effort supported with funding from the Robert Wood Johnson Foundation,<sup>10</sup> which concluded (among other findings) that institutions tend to focus only on their particular role in the system and fail to consider how they can work cooperatively and collaboratively with other institutions and address food safety as a systems-level problem. This “stovepipe” way of working impedes information-sharing and collaboration. Taylor emphasized that much more work is needed to foster an integrated, systems-level approach to food safety.

Taylor also emphasized, however, that it is enormously gratifying that “policy makers at the legislative level are getting this.” He pointed to several signs that the issue of food safety is on the public policy radar screen:

- FDA’s *Food Protection Plan* and the Bush administration’s *Import Safety Action Plan*, both of which are focused on forging better interaction between government and industry in order to improve risk management of both imported and domestic food safety systems-level problems.
- Hearings for the 110th Congress on the *Salmonella* Saintpaul outbreak, which Taylor noted were particularly noteworthy with respect to how members of both sides of the aisle “really dug into what was going on at the institutional level in terms of the interac-

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<sup>10</sup> The project, “Exploring Opportunities to Improve the Nation’s Food Safety Information Infrastructure,” was sponsored by the Food Safety Research Consortium (FSRC), a collaboration among seven research institutions. The goal of the project was to address issues relating to how food safety data are collected and shared. The FSRC issued a report on the project findings in May 2008.

tion between federal, state, and local agencies” and “embraced the need to address these institutional questions in a serious way.”

- Pending surveillance and outbreak response legislation, including a bill (*Improving Food-borne Illness Surveillance and Response Act of 2008*, introduced by then Senator Barack Obama) that would, among other changes, call for an enormous investment in strengthening state and local capacities to be integrated into a national food safety system.
- Pending FDA food safety legislation (i.e., the Durbin bipartisan *FDA Food Safety Modernization Act*), which like the surveillance and response bill would address other institutional issues.

Taylor remarked that it is terrific that food safety, particularly the institutional issues of food safety, is being seriously considered at the national policy and legislative level. It is incumbent upon the food safety community at large, however, to take advantage of this remarkable and unprecedented interest and figure out how to actually achieve better institutional integration. Taylor identified four key elements of success—steps that the food safety community must take in order to fulfill the vision of a more integrated system:

1. *Clearly define responsibilities and roles of all institutions* for all situations (e.g., outbreaks, prevention). Taylor noted that while there has been progress with respect to HACCP<sup>11</sup> implementation and a better understanding of the relationship between company responsibility for having preventive safety plans in place and government’s oversight responsibility, there are still many other role and responsibility issues to be resolved, particularly within and among different government levels and agencies.
2. *Build capacity of institutions to meet their responsibilities*. This is particularly important with respect to governmental capacity, especially at the state and local level but also at the federal level. The FDA, for example, is under-resourced and has some serious capacity-building to do. Likewise, the Nation’s “epi function” is woefully underfunded at all levels—federal, state, and local.
3. *Break down barriers* to information sharing and other collaborative efforts among agencies and organizations.

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<sup>11</sup> Based on a set of seven key principles, HACCP (pronounced “hassip”), the Hazard Analysis and Critical Control Point, is a systematic harvest-to-consumption approach to the identification, evaluation, and control of food safety hazards.

4. *Create new mechanisms of collaboration*, both between government and industry *and* across government. Right now, the mechanisms are not in place that would enable these agencies to work together.

In conclusion, Taylor opined that regulators, industry, and consumers are at a turning point in the history of food safety. There have been few times that food safety has been on the radar screen at this political level. While there is rightfully considerable focus on getting the science and policy right, change is not going to happen unless there is also an effort to “get the institutions right.” Taylor expressed hope that this workshop discussion would generate ideas that will help us move forward in that direction.

Following Taylor’s presentation, there was a question about the roles and responsibilities of the courts with respect to improving food safety. Taylor responded that the courts do play a role as overseers of the government and as administrators of the private liability system, as demonstrated by USDA’s experience with the *Salmonella* performance standard for ground beef, but it is not a central role compared to the one agencies are expected to play, in our government system in implementing laws passed by Congress.

This question was followed by a comment by another workshop participant who suggested that the Department of Homeland Security (DHS) might also have a role to play in improving the food safety system, given its critical existing role in customs and border protection, its management of the National Biosurveillance Integration System (which could serve as a key component of information sharing) and its provision of emergency preparedness grants, including some specifically for food and agriculture (i.e., through the Federal Emergency Management Agency, or FEMA). Taylor agreed.

## FINDING SOLUTIONS: CONSIDERING OPTIONS

Taylor’s keynote presentation set the tone for the workshop: a focus on the roles and responsibilities of institutions, U.S. government and otherwise, and the reality that there is still a great deal of work to be done. As he noted in his keynote presentation, food safety is not a new topic of discussion. It has always been an issue, and the global food supply has always had problems. However, food safety is in the national and international spotlight in a way that is has never been before, making *now* an opportune time to seize on this attention and make some desperately needed changes. The question is, what changes are needed and how should these changes be implemented? More specifically, workshop participants considered:

- What can be learned from the science and history of the very safe thermally processed canned food industry (as Donald Zink discussed) and other food safety success stories?
- Equally, if not more important, what can be learned from food safety failures, such as the recent *E. coli* O157:H7 outbreak in Natural Selection Foods bagged spinach (which Will Daniels discussed) and the more persistent problem of *Listeria* contamination in ready-to-eat meat products (which Randy Huffman addressed in his presentation)?
- What are some of the strategic approaches that the FDA, USDA, industry, and other stakeholders have taken or are currently considering (as most of the workshop participants addressed to some extent but which Robert Brackett, Caroline Smith DeWaal, Richard Raymond, Mike Robach, and Stephen Sundlof considered in detail)?
- How about the consumer population—what role can and should food consumers play in reducing food safety risks (as Christine Bruhn considered)?
- Can any of the new advanced detection technologies being developed help the effort, or is the challenge to better utilize already existing and available technologies (as Russell Flowers considered)?
- Finally, getting back to the original question that Groth posed in his opening remarks, what can the U.S. government do to facilitate efforts to improve food safety? More generally, how should the public and private sectors interact? Again, this was a question that many workshop participants and audience members addressed to some extent, either in their presentations or during discussion. Of note, more specifically, Julie Caswell asked: Does the United States need to develop a comprehensive joint public-private approach toward food safety management and assurance, rather than operating on a risk-by-risk basis?

These were just some of the many specifics considered throughout the day. Of note, the two major U.S. food regulatory agencies, FDA and USDA, are housed separately within the executive branch of the U.S. federal government. The FDA is in the Department of Health and Human Services (HHS), whereas USDA comprises its own separate department. HHS also houses the CDC. Much of the discussion summarized in Chapter 4 revolved around fundamental differences in the regulatory approaches of these two separate regulatory agencies.

*Improving Food Safety: Differences in Opinion*

Again, the workshop objective was neither to reach consensus nor articulate any conclusions or recommendations. Rather, the goal was to spotlight concerns, consider options, and engage in dialogue on this timely issue. Indeed, one of the major overarching themes of the workshop presentations and discussion was the wide range of opinions and beliefs about those details. As Christine Bruhn observed in the final discussion of the day, “We have a commonality, and I think we need to grasp that commonality: and that is the desire to make the food supply safer. Where we differ is in some of the details about how to do it.” This was particularly true with regards to the roles and responsibilities of each of the major stakeholders:

1. Government regulatory agencies (i.e., in the United States, the FDA and USDA)
2. Private industry (i.e., food production companies as well as all companies that contribute to any aspect of the food supply chain)
3. The consumer population
4. Academia (and other research institutions)
5. Inter-governmental organizations (e.g., CAC, WHO, FAO)

As an example of the varied opinions and beliefs expressed, one workshop participant was adamant that there should be more governmental oversight on agricultural farms, while others questioned the usefulness of increased oversight. As another example, several participants were enthusiastic about the notion, or “vision,” of a single unified food safety agency, while others questioned the feasibility and usefulness of such an agency. Despite the contention, there was nonetheless some agreement on the need for more communication, cooperation, and coordination between governmental regulatory agencies and private industry. Yet even then, while commending USDA on its communication efforts over the past couple of years, panelist Caroline Smith DeWaal commented that the broader issue is not just the need for more communication between regulators and industry but the need for regulatory agencies to communicate more effectively with *all* stakeholders, including consumers.





## 2

## Recent Outbreaks in Food Products: Lessons Learned from Past Experience

Session moderator Henry Chin<sup>1</sup> opened this first session of the workshop, *Recent Outbreaks in Various Food Products: Lessons Learned*, by reiterating a point that Taylor had made during his keynote presentation: outbreaks, like the *Salmonella* Saintpaul outbreak, provide an opportunity to learn and improve food safety. This session focused not only on past outbreaks but also other experiences in a range of foods (from minimally processed raw produce to highly thermally processed canned goods), and under a range of regulatory frameworks (from the use of GAPs to the use of the very tight low acid can food regulations), as well as lessons learned from research on consumer behavior. This chapter provides summaries of the four presentations in the session and the discussion that followed.

The session began with Natural Selection Foods' Will Daniels describing the sequence of events during and following the 2006 *E. coli* O157:H7 outbreak in bagged spinach (which traced back to spinach packed for Dole by California-based Natural Selection Foods, best known for its Earthbound Farm brand of organic salads and produce). One of the key messages of his talk, *Next Generation Food Safety in Fresh Produce: An Industry Perspective*, was that while Natural Selection Foods has significantly improved its food safety system since the outbreak, there are still a multitude of food safety problems that can arise after a product leaves the farm and which are not being appropriately addressed. Stakeholders operating at all points along the farm-to-table continuum need to bear responsibility. Dan-

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<sup>1</sup> Henry Chin, PhD, is Senior Director of Scientific and Regulatory Affairs at the Coca-Cola Company, Atlanta, GA.

iels reiterated one of Taylor's keynote presentation points: that too many institutions involved with food safety are operating with a "stovepipe" mentality and that there needs to be more communication and collaboration, particularly among institutions operating at different points along the farm-to-table continuum. Daniels commented on the role of audits, arguing that while audits serve an important verification and validation purpose, they are not preventive measures and therefore should not be treated as such. Buyers (including distributors, retailers, and consumers) need to bear some preventive responsibility as well. Daniels also commented on the importance of food safety science and the need to generate trust between industry and regulators so that company-generated data could be shared and utilized in the effort to improve food safety.

Daniels's talk was followed with a presentation on *Risk Management for Thermally-Processed Foods* by Donald Zink of the FDA's Center for Food Safety and Applied Nutrition (CFSAN). Zink used thermally processed canned foods to illustrate what could be accomplished with food safety when "all of the pieces are in place." Canned foods are among the safest processed foods for three reasons: the science is complete, the packaging is well-developed, and consumers are well-educated. Zink identified the first of these factors—the science—as the most important, suggesting that most other processed foods are not as safe as canned foods because the science is still lacking. Not only do we not have a complete understanding of how contamination occurs in many cases, Zink argued, we do not always have the tools necessary for interrupting those contamination events.

In the third presentation of this session, *Lessons Learned in the Meat Industry: Control of Listeria in RTE Meat and Poultry Products*, Randall Huffman, President of the American Meat Institute (AMI) Foundation provided an overview of the history of *Listeria* control in ready-to-eat (RTE) meat products and the U.S. meat industry and U.S. governmental responses. He described the AMI's recognition of a "Cycle of Control," a four-stage cycle involving (1) awareness and detection of the problem/pathogen, (2) enlightenment and the beginning of an understanding of the problem/pathogen, (3) prevention and the implementation of interventions and, finally, (4) predictive measurement of the impact of those interventions and continued learning about which interventions are most effective. Currently, with respect to *Listeria* control in RTE meat products, the U.S. meat industry is in the final state of the cycle, with the number of *Listeria* recalls and the prevalence of *Listeria* in RTE meat products both showing significant downward trends. Huffman described in detail many of the specific steps that the meat industry has taken over these past 20 years in its effort to control *Listeria* contamination, emphasizing the critically important role of using science and data to inform decision making.

In the fourth and final presentation of the session, *Consumer Behav-*

*ior in Managing Food Safety Risks*, Christine Bruhn of the University of California, Davis, described results of recent research on consumer behavior around safe food handling. Most of the workshop discussion up until this point focused on industry activities in food safety and the challenges. Bruhn's presentation was the only presentation of the day that focused exclusively on the consumer population, specifically on what research has elucidated about how consumers manage, or do not manage, food safety issues. A key message of her presentation was that even when consumers know what constitutes safe food handling or behavior, they do not always adhere to the recommendations. Therefore, while consumers do have a responsibility to be aware of food safety risks and to take appropriate actions, the U.S. food safety system cannot rely on consumer education alone. The focus should be on making food as safe as possible.

### NEXT GENERATION FOOD SAFETY IN FRESH PRODUCE: AN INDUSTRY PERSPECTIVE

*Presenter: Will Daniels<sup>2</sup>*

Will Daniels began his presentation with a brief description of Natural Selection Foods. With its Earthbound Farm brand, it is the Nation's largest grower, packer, and shipper of organic produce, with products in 80 percent of all grocery stores across the country. The company produces a total of about 2.2 million pounds of leafy green fresh salads every week and distributes its produce internationally and as far away as Asia.

On what Daniels described as a "fateful" September 14, 2006, the California Department of Health Services (CDHS) informed Natural Selection Foods that the company had been implicated in a nationwide outbreak associated with fresh cut bagged spinach. The next day, with little to no information except that it had been implicated (among several other companies at that point) Natural Selection Foods issued a voluntary recall. Prior to September 14, the government had told the company only that the leafy greens industry in general was on high alert and that the government planned to act early and quickly in the event of any foodborne illness associated with bagged greens. Indeed, they acted quickly. When Natural Selection Foods was implicated, thousands of samples were collected in both the field and the production facility as part of both government and company investigations. Matches were traced to a field that had supplied spinach on the production day associated with consumer infections. However, the source of the contamination was about a mile downwind of the field, with

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<sup>2</sup> Will Daniels, is President of Quality, Food Safety and Organic Integrity at Natural Selection Foods, San Juan Bautista, CA.

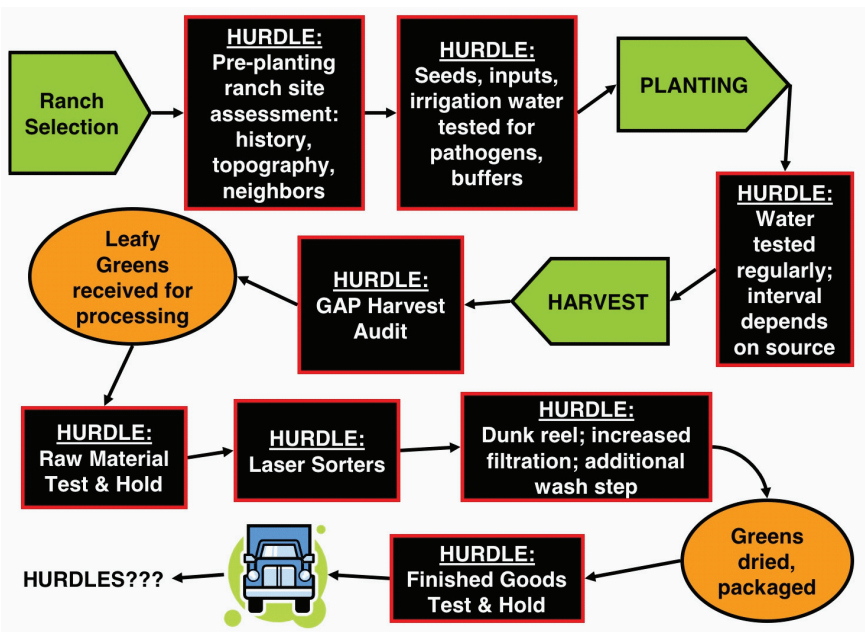


FIGURE 2-1 Natural Selection Foods’ new multi-hurdle approach to food safety.

no clear indication of how the contamination had reached the field itself. Not having that crucial information and without a kill step in their process, Natural Selection Foods was forced to examine the entire spectrum of food safety risk(s) and begin developing a multi-hurdle approach (Figure 2-1) to enhancing food safety which, today, represents a significant improvement in Natural Selection Foods’ safety management system.

Daniels provided an overview of five of the major programs that Natural Selection Foods has established over these past two years as part of its new multi-hurdle approach:

- *Seed to Harvest:* Natural Selection Foods has developed a new plan for enhanced GAPs, including<sup>3</sup>:
  - conducting pre-season ranch assessments of the history, topography, adjacent land use, and other relevant features of all potential ranches;

<sup>3</sup> This is in addition to the 2007 California Leafy Green Products Handler Marketing Agreement.

- testing all seeds, fertilizers, water and other inputs for O157:H7 enterohemorrhagic *E. coli* (EHEC) and *Salmonella* and preventing all inputs from entering the field without certification that they have tested negative;
- during planting, testing water at shorter intervals than required by the California Leafy Green Products Handler Marketing Agreement; and
- practicing regular GAP harvest audits and ensuring compliance in workers' practices.
- *Raw Material Firewall*: The company instituted a raw product test and hold program about two weeks after the September 14, 2006, outbreak, whereby 100 percent of all leafy greens are now sampled from and prevented from entering the process stream until negative results are achieved. In addition to testing for EHEC and *Salmonella*, Natural Selection Foods recently added a *Shigella* screen.
- *In the Plant*: The company has made several enhancements in its packing facilities, for example the use of laser sorters in an effort to reduce foreign materials. The laser sorters identify materials that do not contain chlorophyll and reject them from the process stream. This not only allows the wash systems to focus on the salad itself and not extraneous material, it also reduces consumer complaints about foreign materials in their salads. During the first month of having laser sorter across all processing lines, Earthbound Farm saw a 70 percent reduction in such complaints, which was remarkable given that foreign material complaints comprise about half of all complaints. Now, mostly just weeds still pass through. Additionally, in the wash system, the company has added dunk reels for increased contact time, enhanced filtration time, and added an extra wash step.
- *Finished Product Firewall*: The company added a finished good test and hold program in February 2007, whereby all finished goods are sampled for select pathogens and not released until negative results are achieved.
- *Gaining Deeper Knowledge*: Natural Selection Foods is now using its test data (e.g., from its *Raw Material Firewall* and *Finished Product Firewall* programs) to develop a deeper understanding of what is needed to prevent outbreaks. Importantly, however, Daniels emphasized that testing is not the answer to food safety. The *Raw Material* and *Finished Product* firewalls, for example, are not intended to provide a solution to food safety, rather as a means to "get to the answers" more quickly.

While this multi-hurdle approach to food safety represents a fantastic step forward for Natural Selection Foods, Daniels emphasized that it does not address the multitude of problems that arise after a product leaves the farm and processing facilities—that is, during distribution, storage, retailing and consumption. Food safety does not stop at the farm, nor does it stop in the processing facility. In fact, what happens after products leave the farm probably amounts to more than 50 percent of the food safety continuum, Daniels said, which raises questions about what additional hurdles could be put in place further downstream with the ultimate goal of consumer protection. Daniels reiterated one of Taylor’s key messages: that “real collaboration” among different stakeholders responsible for food safety at various points along this food-to-table continuum is lacking. Too many institutions are still operating like “stovepipes.” In order to achieve progress and reduce risks, these different sectors need to start collaborating. He argued, “Collaboration, rather than competition, among those striving for improved food safety could achieve real results.”

Right now, audits serve as one of the primary mechanisms for communication between different segments of the farm-to-table spectrum (e.g., buyers rely on audits to guarantee that what they are purchasing is safe). But as Daniels asked, “Can audits ensure safety?” He argued that while food safety audits serve as good verification that operators have functional food safety programs, it is really up to the individual operator to ensure that their food safety systems are functioning well. Likewise, further downstream, individual distributors, retailers and consumers need to be responsible for food safety at their respective positions along the food safety continuum. Audits, like other tests, are not preventive measures. Not only are audits not preventive, they are costly. Natural Selection Foods goes through multiple audits yearly, often repetitively for different buyers. Multiple audits cost resources and time, which may be better spent on finding new answers to food safety issues.

Daniels remarked that the same “stovepipe” mentality is at work among research institutions as well. While several universities and trade associations are devoting many resources in an attempt to solve some of these issues, many of these efforts are duplicated. More national-level coordination is needed to reduce the redundancy so that we can find answers more quickly and effectively. Moreover, most of the research is being conducted on foodborne illness in the United States, even though many of these issues are not unique to this country. Nor are they unique to the fresh produce industry. Research results often have more wide-ranging implications than are realized.

Finally, Daniels commented on the large quantity of industry-generated data and how these data have been used against companies in the past (e.g., to implicate a company in an outbreak with which they might not have

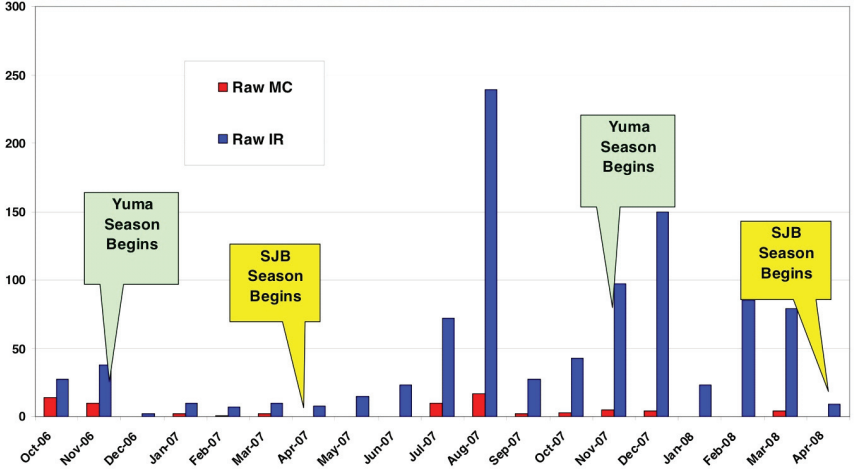


FIGURE 2-2 Initial reactive (IR) and molecular confirmation (MC) data presented by Daniels. Daniels emphasized the spike in contamination events during the summer months (i.e., when operations are moved to San Juan Bautista [SJB], California, from Yuma, Arizona).

otherwise been associated). Government needs to take the lead in creating a trusted, safe environment where data sharing and research collaboration would quicken the pace of concrete, applicable advancements in food safety. “I would love it if we could have an opportunity to share more of the data that we’ve generated through this Test and Hold Program,” Daniels said. “I think that there could be efforts made to protect that data and allow it to be used early on.”

Daniels then gave two examples of the type of safety data being generated at Natural Selection Foods:

1. As shown in Figure 2-2, a spike in both initial reactives (Raw IR) and molecular confirmation (Raw MC) positives of raw product during the summer months, when operations are conducted in the Salinas, California, area (as opposed to the winter months, when operations are moved down to Yuma, Arizona).<sup>4</sup> Daniels remarked that this spike raises questions about whether the company should be spending more of their test and hold monies during the summer months.

<sup>4</sup> Daniels did not comment on the other data spikes (e.g., the IR spikes in November 2007 and December 2007 and the MC spike in August 2007).



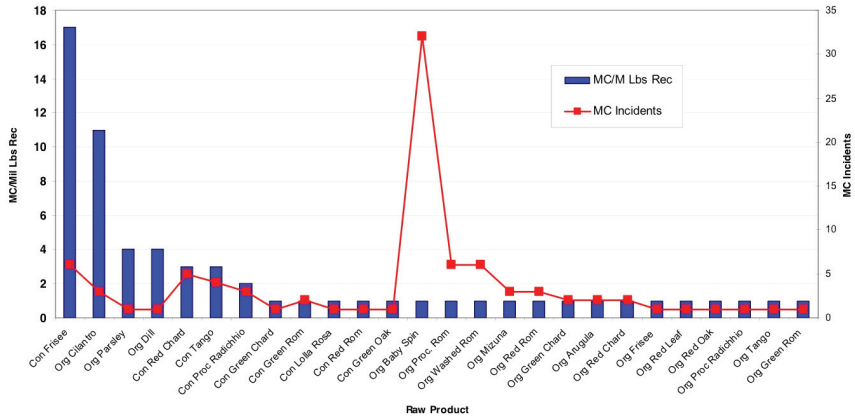


FIGURE 2-3 Data presented by Daniels showing the difference between contamination incidence (number of molecular confirmation positives [MC Incidents]) and prevalence (the number of positives per million of pounds received [MC/M Lbs Rec]).

- As shown in Figure 2-3, a low level of molecular confirmation positives of organic spinach when measured per million of pounds received, or MC/M Lbs Rec (as opposed to molecular confirmation, or MC, incidents). Daniels explained that the low normalized level for spinach is important given that spinach is Natural Selection Foods’ single largest individual ingredient, comprising about 30 percent of the company’s received products (i.e., if spinach was not such a large volume product, the high number of incidents, without taking into account volume, would be more alarming than it is). Daniels also pointed to the high rates for organic cilantro, parsley, and dill, noting that herbs are known to carry a higher risk and that the company has taken additional measures to protect them. He said that the spike for conventional freesia was probably an anomaly and that it was a very low-volume item at the time. When these data were generated, Natural Selection Foods was a mixed operation (i.e., mixed organically and conventionally grown products). Today, the company is 100 percent organic.

Daniels then moved on to the topic of government transparency, commenting on how an FDA official had expressed “surprise” early on during FDA’s investigation of the more recent *Salmonella* Saintpaul outbreak that Florida tomatoes could end up on the West coast. Upon hearing that remark, it dawned on Daniels that the food safety continuum needs not only

better collaboration but also greater transparency. In particular, government needs an industry group that they can really turn to for quick answers during outbreak situations in order to relieve some of the extreme pressure they are under to protect consumers. Too often, outbreaks generate misinformation and media frenzy, which in turn, cause a decline in consumer confidence. This type of misinformation also often leads to the allocation of resources to the wrong places. Having a mechanism in place for government agencies to find quick answers would also alleviate some of the pressure that industry is under during outbreak situations. During the *Salmonella* Saintpaul outbreak, Natural Selection Foods spent an inordinate amount of time reassuring customers that they were distributing neither tomatoes, cilantro, nor jalapeño peppers. Likewise, efforts need to be directed toward helping industry understand government actions and processes better (e.g., during tracebacks).

Daniels concluded by posing the question, “How do we move forward?” He highlighted four necessary steps:

1. Recognize that pathogens exist in our environment and that, in fact our food safety systems control them “99.9 percent of the time.” Natural Selection Foods processed fresh produce for 24 years without an incident.
2. Realize that we are all in this together and that one segment’s efforts alone are not going to solve the problem or reduce consumer concern.
3. Develop national standards and standardized audits (with one audit verifying compliance for all buyers). Standardizing does not mean adopting a one-size-fits-all approach, rather implementing good agricultural and manufacturing processes and having a hazard analysis and food safety plan in place for that particular operation.
4. Collaborate! Companies need to work together as an industry to make our produce safer; they need to create a secure environment where research efforts can be coordinated, applied, and improved; industry and government need to work together such that coordinated efforts can result in quicker conclusions; and we need to develop better trust by establishing transparency and an open dialogue between industry and government.

## RISK MANAGEMENT FOR THERMALLY PROCESSED FOODS

*Presenter: Donald Zink<sup>5</sup>*

Don Zink began by commenting that thermally processed foods are essentially and technically “completely safe” and, as such, illustrates what can be accomplished with respect to food safety and risk management when “all of the pieces are in place.” When failures occur, they are due to mechanical or human errors, not incomplete knowledge about how to manage the risks.

Zink clarified that he would be focusing primarily on commercially and completely sterile products, which comprise just one end of a range of thermally processed foods. Complete sterility is the more extreme: It involves killing even the most heat-resistant thermophilic organisms. Commercial sterilization is not as extreme: It does not necessarily mean that there are no viable microorganisms in the canned product and, in fact, some thermophilic microorganisms usually survive the commercial sterilization process. Rather, it simply means that under the intended conditions of storage and consumer use, those microorganisms are no longer going to continue to grow. Commercial sterility is the standard used today for low-acid canned foods. At the other end of the scale are blanched and pasteurized foods. Blanching is a very mild heat treatment primarily used in the frozen foods industry to fix color and inactivate enzymes that cause undesirable oxidation reactions; blanching may or may not kill some pathogens, depending on how it is done. Pasteurization is usually interpreted to mean that a heat or other form of treatment has been used to destroy harmful microorganisms.

Completely sterile and commercially sterile foods arguably have the best safety record of any category of processed foods. It is difficult to put a number on their safety record, Zink said, given variability in safety and how foodborne disease is monitored around the world. That said the likelihood of contracting botulism or another serious foodborne illness from this type of product is probably less than 1 in 100 billion. Zink identified three major factors that contribute to the safety of canned foods:

1. *The underlying science is defined and complete.* While there are still some unknown things, we do understand and have understood for a long time the nature of several critical processes:
  - a. The physics of heat transfer. Methods to measure the rate of heating among various foods were developed more than

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<sup>5</sup> Donald Zink, PhD, is Acting Senior Science Advisor and Senior Food Scientist at the FDA's Center for Food Safety and Applied Nutrition, College Park, MD.

- 50 years ago, so we know how foods heat, how different foods heat differently (e.g., dried beans heat differently than diced carrots) and how heat is transferred into a container from a piece of processing equipment. We also have well-developed methods for verifying the adequacy and uniformity of heating.
- b. Thermal bacteriology. While there is always some worry that a new, heat-resistant “superbug” is going to emerge, we understand the nature of the bacterial flora that exists now. We have identified all of the important target bacteria for heat processing, we have studied their heat resistance and inactivation kinetics, and we have established target values for what kind of inactivation we must have in order to make products safe. Interestingly, all of the heat-resistant microbial organisms of public health concern are actually less heat-resistant than spoilage organisms, which means that foods need to be heated even more than necessary (from a heat processing perspective) in order to kill the spoilage organisms.
  - c. The engineering of heat processing equipment. We know how to design systems that heat food, we have well-established standards for the design and construction of retorts, and we have excellent process control capabilities.
  - d. Development of tools for accurately and continuously measuring the process. While new microwave and other technologies are being developed for this purpose, we have other tools available that give us an excellent fundamental understanding of what is going on. In fact, the basic critical variables in thermal processing are relatively easy to measure and document (i.e., temperature, time, flow rate, pH, water activity [ $a_w$ ], viscosity, thermal diffusivity, heat and temperature distributions).
2. We have well-developed packaging systems. Zink remarked that it doesn't do any good to produce a safe food if you can't keep it safe before it is in consumer hands.
    - a. We have a very long history with the metal can and glass jar, with the former dating back to Napoleonic times. So the packaging technology is well worked out—so well worked out that it is possible to request from a vendor a certain type of container for a certain amount of material, longevity, thermal resistance, etc., and the vendor can meet that request. For example, if you wanted a metal can that lasted 20 years, we could do that. Today, most metal cans typically last up to about four years. Similarly, if you wanted a glass jar that could survive any amount of trauma, again we could do that, although it would

- be heavy and expensive. We have had substantial experience with flexible pouches and cardboard laminates as well. While they may not date back to Napoleonic times, these types of packages have been on the market for decades.
- b. We have well-established durability standards for all types of common packaging, including standardized testing protocols that could be used to determine whether your product has a reasonable chance of holding up in the marketplace.
3. We have well-educated consumers.
    - a. Nearly every consumer is familiar with the metal can, with the vast majority of consumers understanding that swelling or leakage means that there is some kind of problem. Most consumers are also aware that a badly dented can is suspect. There is some concern, however, that there may be a downward trend in this area, with fewer consumers being aware of potential problems. Not only is there a lot of new packaging entering the marketplace (and taking the place of the metal can), there is less food safety education occurring in the home.
    - b. That said, consumers seem to be transferring what they know about the metal can to some of these other forms of packaging. If a consumer sees a swollen pouch, for example, he or she might suspect that something is wrong.
    - c. Either way—with both canned and other types of packaged foods—mechanical or human errors are to some extent caught by consumers.

In conclusion, Zink re-emphasized that the main value of considering the food safety record of thermally processed foods is to contrast it with other types of foods (e.g., fresh produce), and identify and understand those components that give the former a much better safety record. One of the most important components is science. Technically, complete food safety requires a complete understanding of how all the variables contribute to potential contamination problems and a complete understanding of how to build the tools needed for interrupting those routes of contamination (as well as the tools needed for measuring and controlling the process).

## LESSONS LEARNED IN THE MEAT INDUSTRY: CONTROL OF LISTERIA IN RTE MEAT AND POULTRY PRODUCTS

*Presenter: Randall Huffman<sup>6</sup>*

“The battle with this organism [*Listeria*] has caused more change for producers of RTE deli meat products than any one single factor or event in the last 30 years. Our scars are numerous and deep.”

—John Butts, Vice President of Research, Land O’Frost

Randall Huffman began his presentation by remarking that he would be focusing on the control of *Listeria monocytogenes* in RTE meat products (which, he remarked, fall within the mild heat/pasteurization category on Zink’s thermal heat treatment continuum). Over the last 30 years, the food industry has made remarkable strides in not only understanding the *Listeria* problem and how to control it but also implementing those control measures in its large processing plants.<sup>7</sup> Also in his opening remarks, Huffman reiterated what Taylor had emphasized in his keynote address: that industry plays the primary role in producing food and producing that food safely. After all, not only is selling safe food good for consumers, but it is also good for business.

Efforts to control *Listeria* in RTE products began in the mid-1980s and early 1990s, following an outbreak in California associated with Mexican-style cheeses. Some additional major outbreaks in the late 1990s further emphasized the importance of *Listeria* control in the processing environment. Following a major outbreak and large recall of sliced deli meats in 1998, the industry experienced a one percent reduction in sales. So not only was the implicated company hit, but the rest of the industry as well. This and other similar experiences not only led to a recognition around that time that this is indeed a serious problem, but it also prompted the industry to take a collaborative approach in an effort to solve the problem. At that time, the American Meat Institute (AMI) and other trade associations developed the industry’s first *Listeria* guidelines and best practices, which have evolved since then.

The U.S. government contributed to the effort as well, beginning with its initiation of surveillance by the CDC and product sampling of RTE

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<sup>6</sup> Randall Huffman, PhD, is Chief Food Safety Officer of Maple Leaf Foods, Inc., Toronto, CA. At the time of this presentation he was President of the American Meat Institute Foundation.

<sup>7</sup> Huffman noted that while *Listeria* exists in the home, in our kitchens and refrigerators, and while some of what he would address during this workshop could be applied there, the focus of his presentation would be on what industry has done to control the problem in the large processing plants.

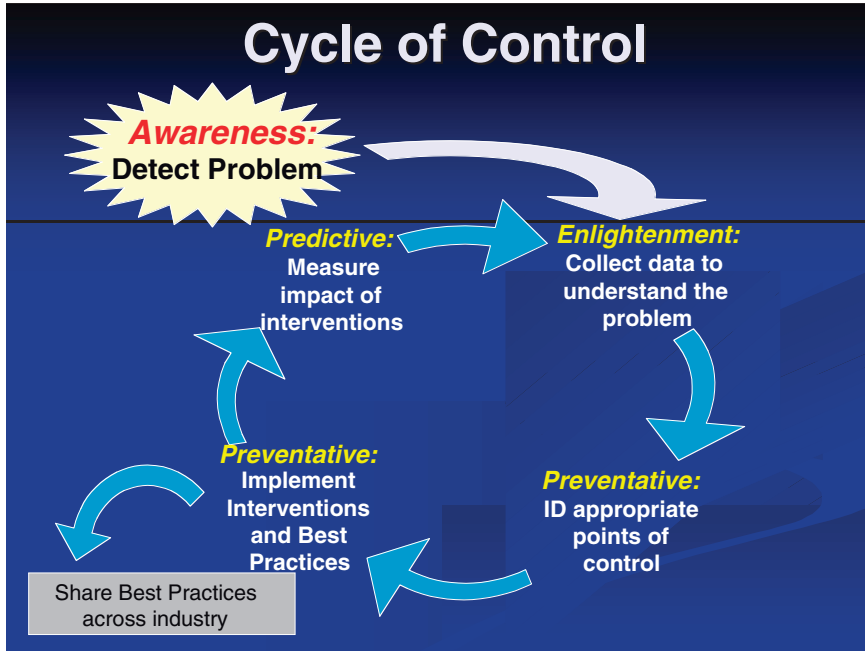


FIGURE 2-4 The four stages of the AMI’s “Cycle of Control,” a data-informed approach toward dealing with *Listeria* and other pathogens.

meats by USDA/FSIS (both in the late 1980s). Later, the USDA/FSIS ratcheted up both RTE product and plant testing, and the CDC initiated two new programs (PulseNet, a system for rapidly identifying large multi-state outbreaks; and FoodNet, an active foodborne illness surveillance system). In the early 2000s, the USDA and FDA completed a major risk assessment and found that deli meats and non-reheated hot dogs topped the list among high-risk foods with respect to listeriosis. More recently, FSIS has begun conducting not-for-cause *L. monocytogenes* verification testing, which involves very aggressive sampling of plant facilities.

The American Meat Institute Foundation recognizes four stages of what it refers to as the “Cycle of Control” with respect to controlling *Listeria* and similar pathogens (see Figure 2-4):

1. *Awareness* and detection of the problem;
2. *Enlightenment* and the beginning of an understanding of the problem;
3. *Preventative* identification of the best points of control in the process and the implementation of interventions, along with a sharing of best practices across the industry; and

4. *Predictive* measurement of the impact of these interventions and continued learning about which interventions are most effective.

Huffman spent most of his presentation time elaborating on each of these stages of the “Cycle of Control” with respect to industry actions in response to *Listeria* in RTE meat products. He provided a list of actions taken by industry at each of the four stages:

1. *Awareness* in the early 1990s
  - The meat industry recognized the environmental nature of the problem (i.e., that the pathogen existed in the refrigerated environment of the processing facility) and started sampling not just products but also contact surfaces in the processing equipment that could potentially serve as growth niches for the bacteria.
  - An important growth niche was discovered in the hollow rollers on the conveyors transporting products. In fact, hollow rollers have since been identified as a major growth niche for other microbes as well (i.e., hollow rollers that are *not* disassembled, cleaned, and heat-treated or otherwise sanitized so as to eliminate bacteria and other pathogens). As it turns out, during pressure washing of the equipment every night, organic matter can be blown into the center of a hollow conveyor roller and create an opportunity for *Listeria* to become established and grow and subsequently potentially contaminate product.
  - There was also a recognition of the benefits and needs for separation of the RTE area from the non-RTE or raw area of the facility. As a preliminary solution, the processing facility floors were painted with yellow lines to keep workers on one side or the other. This approach of using lines to demarcate RTE from raw areas had limited effectiveness and was difficult to maintain over time.
2. *Enlightenment* in the mid-1990s
  - Equipment teardown and a “Seek & Destroy” approach to positive test results became common practices.
  - Steps were taken to redesign equipment and re-engineer equipment to eliminate areas of equipment that were potential growth niches, such as hollow rollers. As a preliminary solution, this re-engineering was an internal process conducted by company maintenance personnel, not equipment suppliers.
  - Equipment suppliers were informed of design problems. Initially, this was the source of a lot of tension and confrontation,



with equipment suppliers hearing many mixed messages from companies about what was needed.

- Floor problems persisted. Today there is an expectation that all drains are *Listeria*-free. Back then, the expectation was that all drains were a source of contamination. No method of floor cleaning seemed to work.
  - Companies started persistent deep cleaning of their equipment, including parts that were not normally disassembled during routine cleaning.
  - There was recognition that many facility areas, including the walls and absorbent materials in refrigerator doors, were a source of contamination. As with the hollow roller, this is an area where equipment suppliers were not initially but would eventually become involved in the effort to re-engineer materials that would not harbor *Listeria*.
  - There was a realization that mid-shift cleanups were contributing to, not helping, the problem. Back then, mid-shift cleanups were common practice—until we realized that bringing water into the processing environment during processing could result in the spreading of contamination.
3. *Preventative* phase of the late 1990s
- Related to the last bullet point, there was a realization that keeping the floor and other parts of the processing environment dry during processing gave a much better chance of controlling the bacteria.
  - Cooking/pasteurization of equipment became commonplace. Today, many companies are actually applying heat or steam to their slicing and other stainless steel equipment for more effective sanitization in addition to regular cleaning and sanitization. Depending on the type of equipment, companies are using steam injected under a tented area, or even placing the entire piece of equipment in a smokehouse.
  - Large area sampling of food contact and environmental surfaces became commonplace (instead of the small grid sampling or the use of small swabs which had been regular practice previously).
  - There was a growing understanding of how organisms spread from growth niches to transfer points (e.g., worker hands or bins used on multiple lines) and how the latter could be used effectively as an indicator site in an environmental testing program.
  - Companies began engineering a physical separation of RTE areas, rather than simply painting yellow lines on the floor.

4. *Predictive* phase from 2000 until today
  - AMI began a series of best practices workshops, based on the large amount of work done in the industry to achieve consensus on how to control *Listeria*, with the first one held in June 2000. AMI has conducted 15 of these workshops over the years, reaching more than 1,000 industry employees. The workshops are organized around AMI's six "Strategies for Control":
    - i. Prevent *Listeria* growth in a niche or other site that can lead to RTE product contamination.
    - ii. Implement appropriate post-lethality technology to eliminate, reduce, or prevent the growth of *Listeria*.
    - iii. Implement a *Listeria* sampling plan to assess in a timely manner whether the processing area is "under control."
    - iv. Respond to each positive product contact sample as rapidly and effectively as possible.
    - v. Verify that the problem was corrected.
    - vi. Review and analyze data to ensure the *Listeria* control program is working.
  - In October 2001, the AMI declared that food safety was a non-competitive issue, which contributed to companies sharing information and best practices more widely.
  - Today, the industry has *Listeria* under control in most large processors and many mid- to small-size processors, with most companies able to identify and control specific growth niches and some companies using very aggressive sampling methods and early warning systems. In fact, many companies are now focusing their sampling efforts in zone 4 (e.g., employee welfare areas), indicating that good control has already been achieved in the critical zones. Several companies have achieved new levels of control (e.g., one year without having a drain test positive).
  - Pasteurization of slicing logs has become commonplace (i.e., after a product goes through the normal thermal processing step, it is removed from its container and the surface is pasteurized again before going onto the slicing line).
  - The use of DNA analysis as a way to identify sources of growth niches and the degree of the diversity in strains in a given facility has become more commonplace.
  - The supplier industry is now using AMI's set of 11 principles for the sanitary design of equipment, not just during the engineering phase of their product development but also during marketing as a way to promote their equipment. When you

open up a meat industry trade magazine, Huffman noted, you'll see these ads.

- Likewise, companies responsible for building RTE processing facilities utilize AMI's set of 10 principles for sanitary facility design.
- Lactate and diacetate are recognized as ingredients useful in the control of *Listeria* growth over the shelf life of a product.
- According to officials at the USDA/FSIS, there have been no foodborne illness-related *Listeria* investigations in RTE meat products for six years. All recalls of RTE meat products for *Listeria* over the past five years have exclusively resulted from products testing positive after not being held by the manufacturer prior to being shipped.
- The sanitation control of growth niches is much better understood today (i.e., the necessary degree of equipment disassembly, chemical sanitizer treatment, hand scrubbing of contact surfaces, heat treatment, non-daily scheduled sanitation, and effective Good Manufacturing Practices (GMPs) after flooding of sanitizer). These efforts are very aggressive, time-consuming, and expensive, but they do work.
- Finally, the nature of high-risk situations is understood much better today than it was 30 years ago. Usually, when a product in the marketplace tests positive, one or more of these high-risk situations is at the root of the problem (which means that eliminating these is key to *Listeria* control): drain backup, the use of high pressure water or air on the floor or in a drain, movement or significant modification of a packaging line, an equipment breakdown, the interchangeable use of personnel between raw and cooked products, construction in or adjacent to the cooked product area, a warm room, a wet area or process, a water-retaining crack in the floor or cleaning of equipment while on the floor.

In addition to all of the above listed changes, new knowledge gained over the past few decades has also led to the "myth-busting" of several misconceptions about *Listeria*. Myth-busting, Huffman argued, is important in food safety. Otherwise, misconceptions become dogma and a lot of time and resources are wasted chasing insignificant issues. Huffman listed a few examples of misconceptions around *Listeria* control in RTE processing:

- Myth: *Listeria* is airborne. Fact: *Listeria* aerosolizes and moves around during high-pressure water cleaning, but it is not airborne.

- Myth: All raw meat is positive for *Listeria*. Fact: Thermal processing kills *Listeria*.
- Myth: *Listeria* cannot be removed from the processing environment. Fact: *Listeria* can be removed from the processing environment.
- Myth: Drains will always be positive. Fact: This is no longer true.

In conclusion, Huffman summarized lessons learned from the meat industry's experience with *Listeria*:

- We need to rely on science and data to inform our decision-making and guide this "Cycle of Control."
- Sampling and testing must be used strategically and aggressively.
- Vigilant and constant re-evaluation of the risk management system is critical.
- Industry sharing of best practices is important.
- Myth-busting is important. Use the data and avoid misconceptions.
- A flexible regulatory approach enables companies to do their job.

The meat industry has put these lessons to good use. Huffman showed data on the number of *Listeria* recalls since 2003 and the prevalence of *Listeria* in RTE meat and poultry products since 1990. Since 2003, there have been 73 recalls, but none of these recalls has resulted from an illness investigation. Huffman noted that all have been due to products testing positive but nonetheless being shipped into commerce, a problem that the industry continues to work on (i.e., encouraging companies to wait to ship product until test results have been returned). With respect to the prevalence of contamination in RTE products, there has been tremendous progress since 1990, from about 4.5 percent positive test results in 1990 to about 0.3 percent positive today. Similarly, based on CDC FoodNet data, we have seen a remarkable decline in the incidence of foodborne illness from *Listeria* over the past 10 or more years, with the incidence per 100,000 at about 0.5 in 1996 and just slightly over 0.25 today (0.25 is a U.S. *Healthy People 2010* objective). Most of that improvement occurred in 1999 and 2000, however, which raises the question: Why hasn't there been any further improvement, especially given that RTE meat products are among the highest risk foods and that the prevalence of foodborne illness associated with this product has declined sharply during this timeframe?

## CONSUMER BEHAVIOR IN MANAGING FOOD SAFETY RISKS

Presenter: *Christine Bruhn*<sup>8</sup>

Bruhn began her talk by commenting on a number of factors that have led to the growing proportion of the U.S. population at increased risk for a foodborne illness:

- *Changing population demographics*, for example the growing proportion of people who are 65 years of age and older and the growing number of people who are diabetic. Older people and people with diabetes are both at a higher risk of foodborne illness.
- *Changing food preferences*, such as the growing number of people who consume raw fruits and vegetables and other minimally processed foods. Raw products do not have a kill step, which means that any pathogens that might be present pose a risk. This includes raw products that would otherwise be safe with pasteurization (e.g., raw milk). Bruhn pointed to a growing interest across the United States in raw milk and the growing number of testimonials as to the miraculous health-enhancing properties of raw milk, despite any scientific backing of these claims. She noted that many states are considering changing their regulations to enhance availability for the public. Bruhn said that this is a growing area of concern because of the increased risk in foodborne illness associated with raw milk consumption. Last year in California, for example, a number of children who had consumed raw milk ended up in the hospital with HUS (hemolytic uremic syndrome).
- *Changing food safety knowledge and behavior*.

Bruhn remarked that the focus of her presentation would be on the last factor: consumer knowledge and behavior around food safety. Bruhn proceeded to summarize key findings from several recent research studies on consumer knowledge and behavior, beginning with a study showing that most people do not know who is at the highest risk for foodborne illness (Byrd-Bredbenner et al., 2007).<sup>9</sup> Fewer than 6 percent of people surveyed were able to identify high-risk groups (i.e., older persons, youth, those with certain medical conditions, pregnant women, and people who are diabetic). The problem with this alarmingly low number, Bruhn explained, is that we have fallen into a rut of doing things that might not be so risky when

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<sup>8</sup> Christine M. Bruhn, PhD, is a Food Science Marketing Specialist and Director of the Center for Consumer Research at the University of California, Davis.

<sup>9</sup> Byrd-Bredbenner, C., J. Maurer, V. Wheatley, D. Schaffne, C. Bruhn, and L. Blalock. 2007. *Journal of Food Protection* 70(8):1917-1926.

we are healthy and then continuing those practices even when we enter a riskier state or are involved with preparing food for people who are in a high-risk group. Even those who prepare food for high-risk individuals are not always aware that their audiences are at high risk. The same study showed that community volunteers who serve meals to senior centers and elsewhere (e.g., community and youth groups, Rotary and other service groups, church groups) do not recognize that some of those they serve may be among the highest risk groups for foodborne illness: 21 percent of those surveyed did not realize that seniors are at increased risk for foodborne illness; 26 percent did not realize that youth were an increased risk; 26 percent did not realize that people with certain medical conditions were at an increased risk; 48 percent did not realize that pregnant women were at an increased risk; and over half (56 percent) of those surveyed didn't realize that people with diabetes were at an increased risk. Because they did not know that these people were at an increased risk for foodborne illness, the volunteers did not know that they should be taking even more than normal precautions when serving these audiences.

In another study designed to see if educational programs have made a difference in attitudes and knowledge, little change was observed between 1999 and 2002 with respect to the percentage of people who had not followed certain food safety guidelines (Cody and Hogue, 2003).<sup>10</sup> For example, in 1999, 9 percent of survey respondents acknowledged that they had forgotten to wash their hands before cooking, compared to 10 percent in 2002. While these percentages are relatively low, the lack of any improvement between 1999 and 2002 (i.e., before and after initiation of a nationwide food safety campaign to educate consumers about key food safety messages) suggests that while food safety educational programs are very important and necessary, they have not had as major an impact as hoped. As another example, in both 1999 and 2002, 29 percent reported not having changed their kitchen cleaning cloth or sponge at least weekly. The great percentage of people who are not changing their dishcloths at least weekly (and some experts would recommend that dishcloths be changed every day or even every meal) suggests that people do not recognize that moist food-laden sponges are environments that bacteria love. As a final example, 22 percent of respondents reported using a meat thermometer in 1999, compared to 25 percent in 2003. So there was some slight improvement. Again, most people are using their thermometers for large pieces of meat, like roasts, and not for smaller pieces of meat that are cooked more frequently

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<sup>10</sup> Cody, M. M., and M. A. Hogue. 2003 (September). Results of the Home Food Safety—It's in Your Hands 2002 survey: Comparisons to the 1999 benchmark survey and Healthy People 2010 food safety behaviors objective. *Journal of the American Dietetic Association* 103(9):1115-1125.

and are more frequently associated with food illnesses (e.g., hamburgers). These numbers indicate that there has not been much progress over time and there is still a long way to go.

With respect to food storage, again, a number of people are unaware of the value of making foods cold as quickly as possible. A survey by Cody and Hogue (2003) (see footnote 10) found that 16 percent of respondents thought it was acceptable to store cooked meat at room temperature, and 50 percent thought it was necessary to cool food to room temperature before refrigerating. Among the food preparation volunteers surveyed in the United States, only 56 percent knew the recommended refrigerator temperature (and thought that it was okay to set it higher than 40 degrees). Nationwide, 40 to 56 percent do not know the recommended refrigerator temperature. The same study showed that people confuse safety with spoilage and believe that food that looks, smells or tastes differently is contaminated. Again, among the same volunteer survey population mentioned previously, 95 percent of survey respondents thought that they could tell if food was contaminated by how it smelled or tasted. Of course, that is not the case.

Research also shows that people also often overstate their compliance and practices. For example, a review of the literature (Redmond and Griffith, 2003)<sup>11</sup> showed that while 82 to 100 percent of people indicated that they knew that it is appropriate to wash their hands after handling meat and poultry, 75 to 100 percent failed to actually do so after handling raw chicken. Bruhn mentioned that some of her current research involves using video cameras to watch study participants prepare food in their own homes to see whether they do what they say they do. She emphasized that there is a large difference between knowledge and behavior.

Sometimes people are confused about date labeling, which is an area where Bruhn suggested that industry could provide some assistance. Sometimes finding the date is a challenge, particularly for an aging population—sometimes the lettering is too small or not clearly visible on the package. Additionally, consumers are often confused by “manufactured by,” “sell by,” “use by,” and “best used by” dates. A recent study by the Food Marketing Institute (FMI)<sup>12</sup> showed that more people are concerned with the “best used by” date than the “use by” date even though the former is intended for quality, not safety. The differences among these dates have not been communicated to the public.

The good news is that people are concerned about pathogens, as they

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<sup>11</sup> Redmond E. C., and C. J. Griffith. 2003. Consumer food handling in the home: A review of food safety studies. *Journal of Food Protection* 65(1):130-161.

<sup>12</sup> Food Marketing Institute Research Department. 2008. Consumers and Food Safety. In *U.S. Grocery Shopper Trends*. Arlington, VA: Food Marketing Institute. Pp. 71-77.

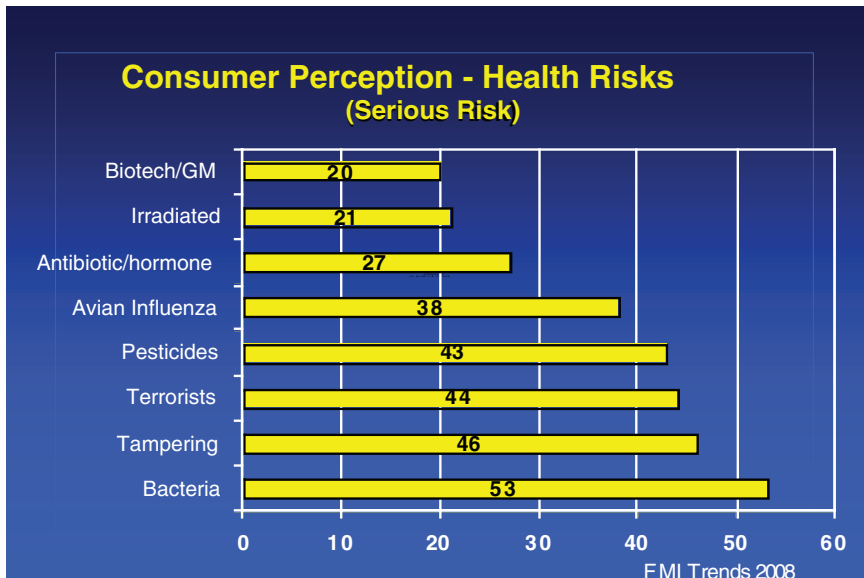


FIGURE 2-5 Data from the FMI show that people appropriately view bacteria as the number one food risk (SOURCE: Food Marketing Institute Research Department, 2008. Consumers and Food Safety. In *U.S. Grocery Shopper Trends*. Arlington, VA: Food Marketing Institute. Pp. 71-77).

should be, according to other FMI data. As shown in Figure 2-5, more people are concerned about pathogens than they are pesticides, additives, irradiation, and genetic engineering of their food products. So people are viewing risks appropriately for the most part. The problem, Bruhn emphasized, is the large difference between knowledge and behavior with respect to food handling and consumption. Research shows that many people do not adhere to safe food handling recommendations, suggesting that the focus should remain on making food as safe as possible. Bruhn noted that it is interesting that people are so concerned with irradiation and genetic engineering, two techniques that could be used to overcome both the pathogen and pesticide residue issues.

Bruhn posed the question, “How do people respond when there is a safety concern?” Again, according to FMI data, when spinach was associated with a food safety risk in 2007, about 74 percent of consumers said that they stopped purchasing spinach. Of course, they didn’t have a lot of choice since it was withdrawn from the market. But, Bruhn asked, why not 100 percent? In 2008, when peanut butter was associated with a food safety risk, 22 percent of consumers stopped buying peanut butter. Again, why wasn’t it higher? Bruhn suggested that perhaps people bought other brands



(i.e., brands not implicated in the outbreak). Or perhaps they believe that “it can’t happen to me,” or maybe they are simply unaware of recalls.

That some people are unaware of recalls raises the question, where do people get their information about recalls and other food safety issues? FMI data (see above) have shown that most people get their information about recalls and other food safety issues from, first, the TV (slightly over 50 percent of consumers get their information from the TV) and, second, the Internet (about 45 percent)—then newspapers (about 35 percent), friends (about 25 percent) and magazines (20 percent). Although none of these sources are trusted very much, with the Internet and TV being trusted almost equally (i.e., less than 20 percent of respondents trust either source) and the newspaper, friends, and magazines trusted by less than 10 percent of consumers.

How do people respond to food recalls when they do know about them? FMI data show that about 81 percent of people check the food in their home. Bruhn questions that percentage, however, given the low percentage of people that actually return food to their supermarket. Half of consumers (50 percent) rely on their supermarket to either offer safe food in the first place or get it off the shelves before they can buy it. Only about 40 percent of consumers are sufficiently concerned that they would be willing to sign up to receive an email alert in the event of a food recall. So basically, with only 40 percent willing to take the effort to be told when a food recall is in effect, food safety is not a high priority for most consumers.

Finally, getting back to the issue of changing population demographics, one might expect people in higher risk groups to manage their own food safety risks more efficiently. But data show that even among people with HIV/AIDS who have received food safety education information, still many people are not following appropriate food safety guidelines. In one study (Hoffman et al., 2005),<sup>13</sup> only about half of those surveyed reported that they were currently washing their hands before preparing food, with another 45 percent saying that they would definitely or probably wash their hands in the future. While that total—95 percent—is pretty good, why isn’t it 100 percent? And that is as good as it gets. With respect to avoiding rare ground beef and raw shellfish, only about 80 percent of respondents said that they were currently or would definitely be willing to avoid rare ground beef in the future. But with soft cheeses and unheated luncheon meats, only about 60 percent indicated that they were currently or would definitely be willing to avoid these products in the future. So this represents a group of

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<sup>13</sup> Hoffman, E. W., V. Bergmann, J. Armstrong Shultz, P. Kendall, L. C. Medeiros, and V. N. Hillers. 2005. Application of a five-step message development model for food safety education materials targeting people with HIV/AIDS. *Journal of the American Dietetic Association* 105(10):1597-1604.

people who would be mostly likely to manage their food safety risks by accepting and following certain recommendations, and yet they are not doing so. This suggests that current food safety education is not sufficient even for those who one would think would be in greatest adherence.

This last finding raises the question, why are people one would expect to adhere to recommendations not doing so? Bruhn listed several possible reasons:

- Optimistic biases (i.e., people think that “it won’t happen to me”)
- People are too busy
- It is inconvenient (e.g., to use a meat thermometer)
- It is not necessary (i.e., “I’ve been eating this way all my life, and I haven’t become ill”)
- Taste preferences, which often override food safety concerns (e.g., people like the taste of rare ground beef)

Bruhn concluded with a summary of five key points:

1. Foodborne diseases are likely to increase in the future because of changing demographics and population preferences.
2. While at least some consumers stop buying products implicated in an outbreak and are interested in hearing about outbreaks and recalls when they occur, most consumers do not respond to outbreaks or recalls.
3. With the greatest number of people expressing concern about hazardous bacteria (e.g., as opposed to irradiation), people are concerned about the right thing (i.e., the most hazardous risk).
4. Despite this knowledge, many people do not follow food safety recommendations and guidelines.
5. We cannot rely on consumer education to keep people safe, because they are not following the rules. The focus must be on making food as safe as possible, which Bruhn said should include a kill step from the processor before food reaches the consumer’s kitchen.

#### OPEN DISCUSSION<sup>14</sup>

The first question of the discussion was directed to Bruhn, asking whether she had seen any positive trends in terms of consumer acceptance of irradiation as a means of making food safer. Bruhn said that over the last 20 years or so, there have been some people, probably about 10 percent,

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<sup>14</sup> This section is a paraphrased summary of the discussion that followed the four presentations.

who have read about food irradiation and wonder why they can't buy irradiated products in their supermarkets yet. At the other extreme, another 10 percent say they "would not touch [irradiated products] with a ten-foot pole." The vast majority of the people are somewhere in the middle. They are still curious about what it is and why it is used. Bruhn's research suggests that when questions about irradiation are answered with science-based information about the safety and potential benefits, as well as who endorses irradiation, people are willing to approve that additional protection for their families. The one area where data are lacking is in consumer attitudes toward the application of irradiation to leafy greens, like spinach and iceberg lettuce. Bruhn mentioned that she is hoping to conduct a study on this area in the near future and to develop the appropriate educational messages that would allow people to understand the process and how it would affect their families.

Bruhn was also asked (by Doug Podolsky, health editor at *Consumer Reports*) what kinds of pathogens are typically found in raw milk. Bruhn responded, "You name it." She short-listed tuberculosis, Q fever, *E. coli* O157:H7, *Salmonella*, and *Campylobacter*. Bruhn then praised *Consumer Reports* for pressuring legal action a few years ago requiring that raw milk sold in California carry a warning label. She also mentioned a bill currently before the California legislature that would initiate a HACCP plan for raw milk producers and which would generally enhance the safety of these products.

The next question was directed to Huffman with regards to the recent *Listeria* outbreak in Canada. Caroline Smith DeWaal of the Center for Science in the Public Interest (CSPI) asked whether Canada endorses the same safety standards and systems that Huffman described in his presentation. Huffman responded that if the products currently in question are associated with illness, then no, the company in question is not implementing the same control procedures outlined in his presentation, or at least not to the degree that is necessary. Additional steps need to be taken. Huffman mentioned that while companies exporting to the United States should have equivalent systems and the same types of control methods in place, he was unsure of the Canadian regulations for domestic products. Huffman mentioned that, coincidentally, he would be heading up to Canada the week after this workshop to co-lead a *Listeria* workshop at the Canadian Meat Council (CMC) annual technical conference, where he and his U.S. colleagues would be sharing best practices.

Zink was asked whether any data indicate that flexible packaging has been linked to any foodborne illnesses. Zink said "not specifically." Flexible packaging does not have the same durability and integrity as glass jars and metal cans do, however, it does have slightly higher leakage and spoilage rates.

A series of traceback questions were asked of Daniels, beginning with a question about the type of ranches from which Natural Selection Foods gets its produce. Daniels explained that Natural Selection Foods has a variety of relationships with a number of ranches, from partner to contract growers. When asked about what kind of oversight Natural Selection Foods has over these ranches, Daniels explained that they require third party audits for each ranch, as well as compliance with Natural Selection Foods' own GAP guidelines and verification audits to ensure that this is happening. When asked if the company requires any physical sampling of the ranch environment, Daniels said, "typically not." He explained that one of the benefits of their multi-hurdle approach is that if, for example, positive results are obtained for raw materials, those results are obtained quickly enough that Natural Selection Foods can return in real-time (within 16 hours of harvest) to the field from which that crop was harvested for a thorough investigation. At that point, the investigation would include physical samples. The questioner then asked if Natural Selection Foods did any co-packing for other companies and, if so, did they put out other products under different labels? Daniels responded, "yes." Finally, the questioner commented that a key problem with tracebacks in produce is that co-packing, relying on multiple sources for foods, etc.; all create delays, which in turn lead to a loss in public trust. He asked: Is there anything that industry is doing in an effort to organize the farm-to-table distribution in order to avoid this kind of delay during a traceback?

Daniels said that while he understands the need to improve tracebacks for commodities, the system for bag salads is in fact pretty tight. The company's traceback system can trace a finished bag to a ranch within a matter of minutes, with verification of that traceback requiring only two hours. He commented that he was unsure why co-packing should be an issue, since it simply puts more responsibility in the processor's hands. He agreed that recall announcements can be confusing for consumers, with multiple brands listed, but argued that the use of multiple brands is a trend that is not going to disappear. It really is the processor's responsibility to ensure that they have a sound recall plan in place—one that has been practiced and with as many holes poked as possible to ensure that you are ready in the event of a recall.

Chin agreed with Daniels, reiterating that the responsibility falls on the processors and producers to have those systems in place. Our food supply system is global, and foods are going to continue to come from multiple sources—it is a trend that is not going to change any time soon.

Another participant, Nancy Donley of S.T.O.P. (Safe Tables Our Priority), followed up on this last line of questioning, commenting on the fact that the amount of recalled product actually recovered is typically very small. Hopefully that will change now that USDA/FSIS will be identifying

retailers in their press releases, making it easier for consumers to identify recalled products in their homes. And hopefully FDA will go down this same path, Donley said, “Because we should just have one way of doing business in this country and we should all be on the same playing field.” Donley then asked Daniels about the spike in pathogen incidence that occurs in the summer months and whether Natural Selection Foods is doing anything to take extra precautions during that time—not just with respect to testing but also with respect to working the company’s preventive process harder during those months. Daniels responded that the company follows the same standards year-round and that these data are fairly new and that, yes, perhaps there should be a greater focus on the summer months while nonetheless staying vigilant year-round. Daniels also re-iterated that testing is not the answer and that, despite best preventive efforts, pathogens are ubiquitous. Even the strongest preventive programs need to be continually enhanced and improved. Finally, Donley applauded Natural Selection Foods’ aggressive testing for pathogens other than O157 and expressed disappointment that a recent USDA/FSIS position on declaring other EHEC strains as adulterants in meat and poultry products did not advance. She mentioned that one of the excuses given is that the technology for detecting other EHEC pathogens does not exist. She hopes that Natural Selection Foods will share its testing standards with the rest of the industry and with the USDA. Daniels agreed and noted that many of his colleagues have heard him repeat his message “loud and clear” that testing should encompass “the gamut of harmful pathogens.” He mentioned that Norwalk virus is also emerging as a pathogen of concern for fresh produce.

## 3

## The Complexities of Food Safety and Some Strategic Approaches Being Taken

Moderator Janet Beauvais<sup>1</sup> opened the second session, *Strategic Approaches to Outbreak Control*, with a comment on the importance of sharing best practices and integrating not just nationally but also internationally. Indeed, the theme of the global nature of food safety and the importance of international integration figured much more prominently in this session than it did in the first session, with the first presentation, Robert Brackett's *Industry Perspective on Managing Risks in a Global Economy*, revolving around the necessity of adopting a global supply chain management approach toward food safety risk management. Brackett, Senior Vice President and Chief Science and Regulatory Affairs Officer of the Grocery Manufacturer Association (GMA), argued that even "made in the U.S." food products are global products, with suppliers for many products coming from multiple countries worldwide. A key message of Brackett's presentation was that because of the global nature of our food supply, no single company (or country) holds entire responsibility. Ensuring that our food products are safe requires that all components of the global system—from producer to consumer—be functioning the way they are intended to function. Accordingly, GMA has developed and adopted a "Four Pillars of Food Safety" program with a focus on global "supply chain management" and foreign-supplier quality assurance.

Shifting gears a bit, rather than revolving around the complexities of the global nature of the food supply chain, the second presentation of this session, Russell Flowers's *Technological Improvements in Outbreak*

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<sup>1</sup> Ms. Janet Beauvais is the Director General of the Health Canada's Food Directorate.

*Prevention*, revolved around the complexities of the technological nature of outbreak prevention. Flowers, of Silliker, Inc., considered the range of technologies available or being developed for outbreak prevention and the knowledge required to minimize or prevent contamination events. He emphasized the importance of data and re-iterated earlier claims made during the day that even as testing technology advances; testing is not prevention. One of his key messages was that rather than expecting some of the new molecular and other advanced detection technologies to “save us,” we need to better utilize the tools and knowledge that we already have. He pointed to plant facility lay-out as an area where improvements could be made.

Returning to the global theme, the third presentation of the session, Julie Caswell’s *Roles and Responsibilities of Industry and Government in Managing Relationships with Global Food Suppliers*, revolved around the reality that risk management for food safety is a complex endeavor not just because of the inherent risks associated with food production but also because of the diverse nature of our international food supply chains. Caswell provided a conceptual overview of the range of combined public-private approaches to food safety management being used in the United States and elsewhere. Caswell commented that, unlike Canada and the United Kingdom, the United States makes food safety decisions on a risk-by-risk basis. She asked whether it might be possible and beneficial to develop a more comprehensive approach that would allow for more predictive, rather than reactive, food safety decision making.

This chapter provides summaries of these three presentations and the discussion that followed.

## INDUSTRY PERSPECTIVE ON MANAGING RISKS IN A GLOBAL MARKET

*Presenter: Robert Brackett<sup>2</sup>*

Robert Brackett began by remarking that globalization is not something that is coming. It is here. It has changed our view of (1) what food is, (2) what food safety is, and (3) how businesses practice and manage food risks. He addressed each of these in turn, with most of his presentation focusing on the last component: how businesses have changed the way they practice and manage risks, with a growing emphasis on global supply chain management.

As an example of how globalization is changing our view of what food is, consider a loaf of bread that is “made in the U.S.” but which is

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<sup>2</sup> Robert E. Brackett, PhD, is Senior Vice President and Chief Science and Regulatory Affairs Officer at the Grocery Manufacturer’s Association, Washington, DC.

comprised of seven ingredients that could have come from any number of different places on any given day:

1. Wheat gluten from France, Poland, Russia, the Netherlands, or Australia
2. Honey from China, Vietnam, Brazil, Uruguay, India, Canada, Mexico, or Argentina
3. Calcium propionate from the Netherlands
4. Guar gum from India
5. Flour enrichments from China
6. Beta-carotene from Switzerland
7. Vitamin D<sub>3</sub> from China

What ends up being a U.S. product is truly a global product. This loaf of bread is not a unique example, Brackett noted. It is very common, and it complicates how food safety risks are addressed. For example, from 2003 to 2007, U.S. imports of fruits and fruit preparations increased 18 percent; grains and feeds, 40 percent; vegetables and vegetable preparations, 23 percent; oilseeds and products, 63 percent; dairy products, 14 percent; tree nuts and preparations, 18 percent; and poultry and poultry products, 54 percent. The only flat trend has been for livestock and meats, with a slight negative (–1 percent) change between 2003 and 2007. Overall, the last several years have seen a 29 percent increase in U.S. food product imports. Today, more than 20 percent of all U.S. imports are food products, amounting to more than eight million shipments annually. Moreover, about 40 percent of all trade in agriculture, fisheries and forestry occurs between developed and developing countries, which presents its own subset of challenges.

While the specific implications of globalization for food safety are uncertain and continually evolving, Brackett emphasized that one thing is certain: globalization of the food supply means that all countries must share responsibility for food safety throughout the entire food supply chain, from producers to consumers. Ensuring that our food products are safe requires every component of the global food supply system be functioning the way it is intended to function. No single company or country holds entire responsibility.

Brackett made a few comments about consumer confidence and referred to some data analyzed by the FMI showing that the number of consumers who are either “completely” or “somewhat confident” that supermarket food is safe has gone down from 82 percent in 2006 to 66 percent in 2007. According to similar data collected by the GMA in 2008, 52 percent of consumers surveyed reported that they were “more concerned” with the safety of foods produced in the United States compared to two or three years ago. Only 4 percent are less concerned, and 44 percent reported no change in



their level of concern. The numbers are more alarming for imported foods. Compared to two or three years ago, 68 percent of consumers surveyed reported being “more concerned” about the safety of imported foods. Only 3 percent were less concerned, 28 percent reported no change in their level of concern, and 1 percent replied that they “don’t know.” Obviously, globalization is changing the confidence people have in their food supply. Not having confidence in the global food supply means that not only are consumers not trusting food manufacturers or food in general, but they also have less confidence in regulatory and other government agencies and are less likely to react to government advice.

Brackett then went on to discuss the nature of the risks being faced—both what those risks are and why they exist. He identified three main categories of risk:

1. Microbiological
  - a. e.g., *Salmonella* in jalapeño peppers
  - b. e.g., *Cyclospora* in raspberries
2. Chemical
  - a. Unapproved pesticides, which have been particularly problematic in dietary supplement ingredients
  - b. Heavy metals, such as lead in candy
  - c. Unapproved chemotherapeutics, such as chloramphenicol being detected in honey and fish
  - d. Undeclared allergens
3. Physical, including anything from glass to rocks

He listed several reasons why these risks exist:

- a. Non-adherence with GAPs/Good Manufacturing Practices (GMPs)/Good Aquaculture Practices (AqPs)
- b. Poor sanitation (e.g., often something as simple as not having a screen over a window or having appropriate toilet facilities)
- c. Poor water quality
- d. Economic adulteration (e.g., the use of melamine to obtain an economic advantage, the use of an ingredient of lesser quality)
- e. Counterfeiting (i.e., not only of the products themselves but also certificates indicating that an imported product has met a particular standard or audit)
- f. Intentional contamination
- g. Terrorism
- h. Industrial sabotage

The remainder of Brackett's presentation focused on how to manage these risks, with an emphasis on "supply chain management." He began by reiterating Daniels' point that audits are not enough and that food safety risk management requires a higher level vision or strategy. To this end, GMA has developed a comprehensive set of risk management foundational elements (many of which Daniels had identified in his presentation as being important for the produce industry in particular):

- *Industry responsibility*: Food safety and consumer protection is ultimately the responsibility of industry, regardless of regulations or legal mandate, although industry is not the only sector with responsibilities.
  - *Industry needs to establish preventive—not reactive—food safety programs*, even in the absence of regulation (i.e., we must go beyond what is expected by the regulatory authorities).
  - *Regulatory agencies need to provide incentives, not disincentives, for industry* to enhance their safety programs and increase compliance, such as decreased inspection frequencies.
  - *We need more collaboration between industry and regulatory agencies* so that appropriate risk management decisions can be made down the line rather than companies being afraid to reveal too much information because of the likelihood of facing a punitive action or having information shared with their competitors.
  - *Industry needs to manage the supply chain in a way that they have not done in the past.*
- *Adequate funding*: Regulatory agencies need to have the appropriate amount of funding in order to do their job.
- *Adequate authority*: Similarly, regulatory agencies need adequate authority in order to do their job.
- *Adequate and effective training*: Both the private sector plants and public sector regulators need adequate and effective training.
- *Risk-based*: Decisions and strategies need to be risk-based so that the appropriate resources are being focused where they will do the most good.
- *Leveraged resources*: The federal government needs to leverage state and industry resources more than it has been doing.
- *Research*: We need to know what the risks and consequences of our actions are.

Before elaborating further on one singularly important component of this set of foundational elements—the need for industry to manage the supply chain in a way that they have not done in the past—Brackett briefly

described GMA's Four Pillars of Food Safety program, a strategic plan developed in 2007 for addressing industry responsibility for a safe global food supply. The four pillars are:

1. *A mandatory foreign supplier quality assurance program*, whereby suppliers must have written food safety plans that can be verified by both the importer and government.
2. *A voluntary qualified importer food safety program* to serve as an incentive to those companies willing to share data and ensure that they are going above and beyond what regulatory agencies expect (i.e., the incentive is that products will be imported more quickly).
3. *Capability building: foreign focus*: While there are some government programs already actively engaged in this type of activity, the private sector should be contributing as well. In fact, some companies are doing this already, for example by ensuring that products are safe before being exported instead of after being imported.
4. *Capacity building: U.S. broader focus*: The regulatory agencies need to have the resources and authorities they need in order to do their job.

Brackett defined “supply chain management” as “due diligence to assure that products received from suppliers meet required regulatory, legal and contractual standards of safety.” He listed several reasons why supply chain management is important:

- Legal considerations
  - Companies must comply with regulations and laws.
  - Liability poses another legal restraint.
- Financial considerations
  - As learned from the melamine crisis, cheaper is not necessarily less expensive since, in the long run, being cheap could cost not just a company but an entire country considerably more than it would have if the more expensive, higher-quality ingredient had been chosen initially.
  - Both commercial and country brand values are important considerations.
    - Many companies would rather discard millions of dollars worth of food in order to save their brand and their reputation.
    - Countries themselves have brands to protect: when a country is associated with a foodborne illness, it often becomes

very difficult to reassure customers that the country is doing anything right from that point onward.

- Consumer expectations and an implied contract with consumers that products are safe
  - Consumers expect and assume that the products they purchase are going to be safe and, when things go wrong, they put responsibility and blame on both the company that sells the product and the exporting country.

GMA has issued a document, the GMA Food Supply Chain Handbook, published in five different languages (English, Spanish, Mandarin, French, and Russian), that includes a checklist of things that buyers should expect of their suppliers in an effort to “raise the [safety] bar.” While the handbook includes many elements that one expects (e.g., HACCP, GMP, Good Handling Practices [GHP], GAP, and GAQP), it also emphasizes employee training, U.S. regulatory compliance, the importance of recall programs and the importance of product testing.

In conclusion, Brackett emphasized three key points:

1. International trade in foods and agricultural products will continue to increase. We will have to address this. There is no way we can go backward at this point.
2. Managing the supply chain will be essential to assuring safe products and consumer confidence. We will have to find new and different ways of doing this and not just rely on audits, certificates and other traditional tools.
3. The government and private sector **MUST** cooperate if we are ever going to solve the problem of food safety and continue to provide safe products for American consumers.

## TECHNICAL IMPROVEMENTS IN OUTBREAK PREVENTION

*Presenter: Russell Flowers<sup>3</sup>*

Rather than run through a long list of new technologies and processing techniques, Russell Flowers remarked that the focus of his presentation would be on microbial ecology during the food production process and opportunities for technological applications that disrupt that ecology. He noted that there are situations where technological opportunities for prevention exist but are not being utilized.

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<sup>3</sup> Russell S. Flowers, PhD, is Chairman and Chief Science Officer, Silliker Group Corp., Homewood, IL.

But first, what is it that we are preventing? The answer: contamination of foods with pathogens. We do this in three ways, which Flowers referred to as the “3 Ks”:

1. Keep them out. This is particularly important for products that do not undergo a lethal process. There are several ways to do this:
  - Focus on the raw materials/ingredients by practicing GAP with both plants and animals, building quality relationships with suppliers instead of relying on a purchase product mentality, and certifying critical (i.e., at risk) ingredients.
  - Focus on the process environment (e.g., as the meat industry has done with *Listeria*, which Huffmann addressed in his presentation) by improving plant and equipment design and practicing GMP and GHP.
  - Prevent recontamination of processed product.
2. Kill them. Heat is often used for this purpose, as Zink elaborated earlier. Ideally, all products would have a kill step in their in-use containers with no further contamination subsequent to the kill step. There are several technologies available for this purpose:
  - Traditional technologies for killing pathogens include the use of heat, pH/acidity, sanitizers/biocides and irradiation.
  - Newer technologies available for killing pathogens include the use of pulsed electric fields, pulsed light, high power ultrasonics, cold plasma, ohmic heating, UV light, microwave, high pressure, and new biocides acceptable for direct food contact. To date, application of most of these newer technologies is limited to certain types of products.
3. Keep them from growing. In cases where pathogens are present, the goal is to keep those pathogens from growing. Again, there are several ways to do this:
  - Through formulation and packaging (e.g., pH,  $a_w$ , Eh).
  - Through temperature control (either high or low but not in the middle).
  - Through moisture control.

Flowers identified several tools available for accomplishing the 3 Ks: GAP, GMP, GHP, HACCP, cleaning and sanitation, plant and equipment design, and personnel and maintenance practices.

Flowers then posed two questions: (1) What are some of the problems we face, and (2) how might technology be used to solve some of these problems? First, the problems:

- Contamination of pathogen-free tissue during harvest and primary processing. This is a critical issue for the meat industry in particular.
- Contamination of raw material where there is no kill step in the process or preparation. There are several examples of raw material ingredients that don't have kill steps and for which this is a common problem:
  - *E. coli* O157:H7 in fresh meats.
  - *Salmonella* and *E. coli* O157:H7 in produce.
  - *Salmonella* in dry ingredients for chocolate, dry blend diet drinks, etc.
  - *L. monocytogenes* in fresh produce and meats.
  - *Campylobacter* in fresh poultry.
- Process failure: This is often due to a HACCP deviation or recontamination subsequent to the kill step and before packaging.
- Post-process contamination. Again, there are several examples of common post-process contamination problems:
  - *L. monocytogenes* in cooked meats. (Flowers noted that as Huffman elaborated, the meat industry has made significant progress in controlling *L. monocytogenes* in RTE meats, but the process is not foolproof.)
  - *L. monocytogenes* in pasteurized dairy products.
  - *Salmonella* in dry milk products. (You won't find a long list of *Salmonella* outbreaks in dry milk products, Flowers commented, but that doesn't mean that contamination events are not happening prior to products reaching the market. One of Flowers's responsibilities as a practicing microbiologist is to consult with food companies and test products early on, to prevent outbreaks.)
  - *Salmonella* in dry cereals and pet foods. (These are usually due to moisture control issues, which lead to products being re-contaminated after the kill step.)
- Microbiological testing needed to quantify and manage risks.

Most importantly, Flowers emphasized, the microbiological safety of many products is dependent upon preventing the introduction of pathogens during harvest/slaughter and in the post-kill process and packaging environment. In the post-process environment, this means not only preventing the growth of pathogens but also preventing the spread of pathogens from contaminated areas to produce and product contact areas. In order to accomplish this, the *ideal* food plant layout has a separate raw processing area (where all the cutting, sorting, etc., are conducted), a kill step between this area and the next, and then a separate packaging area (see Figure 3-1).

## The Ideal Food Plant Layout

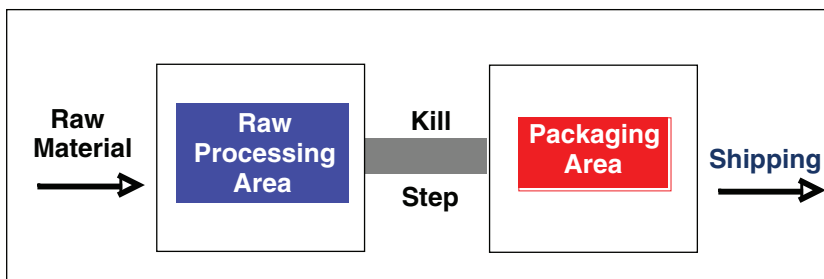


FIGURE 3-1 The ideal food plant layout, as presented by Flowers.

Flowers explained that this ideal food plant layout, with complete separation between the raw and processed product, would minimize one of the most important sources of contamination: the introduction of pathogens in the post-kill process and packaging environment. In actuality, this is not a common layout; most existing facilities have a lot of back-and-forth movement of product and situations where cooked product that has already gone through the kill step is subject to recontamination. Flowers mentioned that, as Huffman alluded in his presentation on *Listeria* in RTE meat products, there are ways to manage this problem, but it requires diligence and a re-design of the plant and the process flows. Some of the industry is doing this very well, Flowers said, but some is not. Unfortunately, one company's failure to manage this problem can affect the reputation of the entire industry. Flowers mentioned that the same problems occur in home and food service operations, where there is a lot of back-and-forth movement of foods and potential exposure of cooked products to contaminated areas.

Flowers then addressed the second question: How do we combat this microbial growth? First, consider what microorganisms need for growth: moisture, temperature, time, nutrients, and the absence of inhibitors. Preventing growth or recontamination in those areas requires controlling each factor:

- Moisture control
  - This limits not only growth but also distribution (e.g., the aerosols created when a forklift travels along a wet floor or when cleaning in one area of the plant creates aerosols that can travel to another area of the plant).

- Temperature control
  - Reducing the temperature can slow or stop growth.
  - Elevating the temperature accelerates growths but only until it reaches a lethal limit, beyond which it can stop growth.
- Time, nutrients, and inhibition control through cleaning and sanitation
  - The ongoing process of cleaning and sanitation starts the clock and limits time, which is important even in refrigerated environments where *Listeria* and other pathogens can grow. In many plants, however, sanitation schedules are set according to shift changes (e.g., every other shift) and not according to what the data indicate the best frequency would be. If the frequency is not fine-tuned, even if a single cleaning and sanitation is effective at that point of time, nutrients and microbes can build up quickly between cleanings.
  - Routine cleaning and sanitation remove nutrients.
  - Cleaning and sanitation also introduce inhibitors.

Next, Flowers listed several technical steps necessary for minimizing the severity of any single contamination event:

- Must identify and characterize the causative agent.
  - There have been many advances in test methodology allowing for faster, more sensitive detection (within 8 to 24 hours). Other technological advances are in the pipeline.
  - Molecular advances have led to the availability of genotyping kits for use by industry. Flowers noted that the technologies upon which these newer industry-available techniques are based have in fact been around “for a while,” in academic and government labs. For example, PulseNet, a CDC program, is a national network of labs contributing to a pulsed-field gel electrophoresis [PFGE] database for use in the identification of pathogenic strains.
- Need to determine the source of contamination of process failure.
- Must have traceability of the product and its ingredients (i.e., not necessarily traceability for recall but traceability of each ingredient in a product).
- Must be able to differentiate between good, suspect, and bad products or product lots, which require having “break points” as well as good outbreak and recall management.
- Must be able to clean up a plant and document effectiveness.
- Must establish and validate preventive measures for the future.
- Must be able to provide verification for initial product runs after a contamination event.



More generally, the industry needs to develop data necessary for understanding the microbial ecology of the process environment; and it needs to use those data to educate employees about microbial ecology, develop criteria for pathogen testing, improve manufacturing facilities, and improve and verify process flow. Also, routine testing is important. Flowers noted that Silliker has encountered many problems that could have been prevented through routine testing. While testing generates large quantities of negative information, it does identify events that require corrective actions.

Flowers elaborated on the need for break points. While challenging, lots must be defined, good data records kept, and break points established. Accomplishing these tasks is particularly difficult for continuous processes, like milk drying and flour operations which can run for a month or more without stopping and where it is difficult to draw a line. It is also a problem for rework situations (e.g., a carcass coming back into a plant). The issue is often further complicated by the lack of reliable test data in the event of an incident or outbreak.

Flowers listed a set of six steps that companies should take:

1. Plan ahead for a potential contamination event.
2. Develop rational break points.
3. Minimize lot sizes to the extent economically possible.
4. Establish processes and related documentations (e.g., records retention policies).
5. Develop a sampling plan (i.e., one focused not so much on lot acceptability but process verification).
6. Test using validated method(s) and credible (i.e., third-party accredited) laboratories. (Flowers noted that while this may seem a biased remark, given his affiliation with Silliker, in fact companies invalidate testing data.)

In his final remarks, Flowers emphasized that while new technologies for killing pathogens are being developed and validated, these technologies will not prevent contamination. While the new testing and traceability technologies are going to continue to improve with respect to speed and sensitivity and while the genetic characterization of pathogens is becoming easier and more automated, we are not going to see any time in the near future a “gun we can shoot at a carcass” indicating the presence of *E. coli* or a particular strain of *E. coli*. Even with this new testing technology, testing is not preventative; its best use is as a way to verify ongoing control. Rather than focusing so much on new technologies that “are going to save us,” Flowers urged better utilization of the tools and knowledge that are already available and adoption of new technologies as they become available. The entire industry needs to be doing this, not just the vast majority.

Even just a small portion of companies not making the effort can cause damage to the reputation of the entire industry.

## ROLES AND RESPONSIBILITIES OF INDUSTRY AND GOVERNMENT IN MANAGING RELATIONSHIPS WITH GLOBAL FOOD SUPPLIERS

*Presenter: Julie Caswell<sup>4</sup>*

Julie Caswell began her presentation by noting “the obvious”:

- First, food safety is a joint effort, with the private sector producing food safety but with government providing oversight and regulation. The private market not only responds to the public regulatory system (e.g., by finding ways to reduce compliance costs) but also, in some cases, gets ahead of regulation (e.g., by differentiating products and adding value based on safety or through first mover advantage). Therefore, the risk management environment encompasses a mixed mode of private and public responsibility.
- Second, in most countries around the world, there has been an ongoing shift in the food safety regulatory approach, from a “command and control” approach to a more “performance” approach that puts the responsibility for food safety production more directly and strongly on the food business operators themselves and which has led to a rapid development of private standards.
- Third, when examining food safety, we are dealing with a very complex and demanding policy space that involves both public and private sector incentives and controls.

Caswell expressed the importance of taking a “big picture” look at control and management of food safety risks, noting three key features worth examining:

1. The complexity of risk management for food safety:
  - a. The set of risks is complex, with varying sources of origination, transfer, and magnification along the supply chain.
  - b. Supply chains are diverse, with both international and domestic food supply chains shifting quickly and in a decentralized manner and often in a way that cannot be picked up on very rapidly at a systematic level.

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<sup>4</sup> Julie A. Caswell, PhD, is Professor of Resource Economics at the University of Massachusetts, Amherst.

2. The need to focus on a mix of private (business and consumer) incentives and public (regulatory) controls.
3. The need to step back and consider generic approaches to the public versus private roles and responsibilities in food safety and risk management and determine which generic approaches are being used and under what circumstances.

Caswell elaborated on the last bullet point and described a range of generic approaches to private versus public involvement (see Figure 3-2 for schematic). On one end of the spectrum, there is *no intervention*, with public agencies having no policies around food risk or risk management and with industry relying solely on private controls. On the other end of the spectrum is *direct regulation*, whereby public agencies are prescribing what companies must do (e.g., with respect to labeling) and prohibiting certain actions, products, and processes. Between these two ends are a range of private/public mixes, including *self-regulation*, such as the use of industry voluntary codes of practice and farm assurance schemes; *informa-*

## Options for Public/Private Actions



FIGURE 3-2 A spectrum of generic approaches to private versus public involvement in global food safety risk management, as described by Caswell.

tion and education, whereby government has the ability to generate and communicate information to consumers and make consumers aware of food safety issues; *co-regulation*, where regulation is the responsibility of a public-private partnership, with statutory or government-backed codes of practice (a popular mode of regulation in the European Union, particularly in the United Kingdom); and *incentive-based structures*, where the amount of regulation is in response to what companies are doing, for example inspection frequencies being conducted based on how well a company has performed in the past. Caswell argued that we do not spend enough time thinking about which of these options best describe our food safety regulations. For example, in which box does regulation of *Listeria* control in RTE meats fit?

In fact, any single box in Figure 3-2 encompasses a range of regulatory approaches. For example, *direct regulation* approaches range from labeling requirements (at the lower end of intervention) to the use of target, performance or product/process standards (a medium level of intervention) to requiring prior approval before a product can enter the market (at the high end of intervention). Even within each of these different levels of intervention, there is variation. For example, using a standards approach (i.e., the medium level of intervention) requires setting a standard (“standard setting”), deciding how the standard is going to be implemented (“process implementation”) and then enforcing and monitoring the standard (“monitoring and enforcement”). Moreover, regulation at each of these sub-levels could be either national or international and determined by either private or public interests. In short, Caswell said, the distinction between public and private regulations is less discrete than often assumed, with most markets having a mix of co-existing public and private safety regulations and considerable interrelationships and dependencies between the two.

Knowing which box and specific regulatory approach is being used and whether it is the right approach in any given food safety situation enables us to ask whether we might achieve better results with respect to both food safety effectiveness and economic efficiency if our regulatory approach were different (i.e., if a different mix of public and private roles and responsibilities might be more effective).

As an example of the variation that exists even within a single regulatory approach, or option, Caswell pointed to a study by Spencer Henson on the rapid development of private standards in food safety management and the range of standards being employed (Henson, 2008<sup>5</sup>). Private standards used to be set predominantly on a business-to-business basis, with individual companies setting their own individual standards. These

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<sup>5</sup> Henson, S. J. 2008. The role of public and private standards in regulating international food markets. *Journal of International Agricultural Trade and Development* 4(1):63-81.

## Examples of Public–Private Mix in UK

United Kingdom	Setting Standard	Process Implementation	Enforcement and Monitoring
ZAP Salmonella Programme	Private (voluntary) (with funding from government and a multi-stakeholder group advising on ongoing developments)	Private (with funding and facilitation from government)	Private (part of farm assurance scheme's requirements) (public sector provides on-farm support and advice to high-risk producers)
Lion Quality Scheme	Private	Private	Private (Third party audits)
Eat Safe Scheme	Public (with a multi-sectoral stakeholder group advising on ongoing developments)	Public	Public (Environmental Health Services)

FIGURE 3-3 Examples of the wide range of public–private mixes with respect to food safety regulation among different areas of food safety regulation (the left-hand column in each table describes the area of food safety regulation considered), as described by Caswell.

individual-level standards were either national (e.g., Nature’s Choice by Tesco in the United Kingdom, Field-to-Forks by Marks and Spencer in the United Kingdom, Filière Agriculture-Raisonnée by Auchan France) or international (e.g., Wal-Mart and Nestle). Henson has shown that, over time, private standard-setting has evolved into a meta-standard approach, where joint standards are used among a group of suppliers or retailers. Examples of these “collective” standards include, at the national level, the Dutch HACCP, the British Retail Consortium (BRC) Global Standard, Assured Food Standards, Qualität und Sicherheit (the “QS system”) and Integrate Keten Beheersing, and at the international level, the International Food Standards, Safe Quality Food (SQF) 1000/2000/3000<sup>6</sup> and GLOBALGAP (formerly EUREPGAP).

As another example of the variation in mixed private-public approaches being utilized, Caswell and colleagues conducted a study for the Food Standards Agency in the United Kingdom looking at private/public mixes across the United States, Canada, the United Kingdom, and Australia (Fearne et

<sup>6</sup> SQI is a food quality certification program managed by FMI.

### Examples of Public–Private Mix in US

United States	Setting Standard	Process Implementation	Enforcement and Monitoring
Biotechnology Introduction	Public–Private	Public–Private	Largely private
<i>Listeria</i> in Ready to Eat Meat	Public (private sector selects options)	Public–Private	Public–Private
Animal ID	Public (states are putting premise ID in place)	Public (infrastructure) Private (voluntary compliance)	Private (voluntary so far)

### Examples of Public–Private Mix in Canada

Canada	Setting Standard	Process Implementation	Enforcement and Monitoring
HACCP Advantage	Public–Private	Public	Private (Third party audits)
Traffic lights system and Dine Safe programme	Public	Public	Public
On-farm Food Safety	Private (with funding from government)	Private (with funding and facilitating measures from government)	Private (voluntary)

al., 2005<sup>7</sup>). In the United States, they examined three areas of food safety regulation: *Listeria* in RTE meats, the introduction of biotechnology, and animal identification. They examined standards setting, process implementation, and enforcement and monitoring (i.e., the three components of the “standards” approach that Caswell had described previously). As illustrated in Figure 3-3, they found a mix of public and private involvement among these three components and across all three areas of regulation.

Also as shown in Figure 3-3, food safety programs in the United Kingdom and Canada employ a range of public-private mixes but are more

<sup>7</sup> Fearnle, A., M. Garcia, J. A. Caswell, S. Henson, and Y. Kharti. 2005. *Exploring Alternative Approaches to the Traditional Modes of Food Safety*. Final Report, Imperial College, London. Prepared for the United Kingdom Food Standards Agency under Control D03004.

consistent in their approach than we are in the United States. The United States is very reactive in its approach, Caswell explained. We make most decisions on a risk-by-risk basis, rather than assigning responsibility for the three different components (i.e., standard setting, process implementation, and enforcement and monitoring). This raises the question: Is there a way for the U.S. regulatory structure to step back and adopt a more comprehensive approach and philosophy toward the public-private mix across a range of risks, rather than dealing with each risk individually? Is there any consensus on the best overall approach to food safety production? How should we assign those responsibilities?

Caswell argued that having a comprehensive approach would mean having a set of criteria for dealing with risks (e.g., if the risk involves *a*, *b*, and *c*, then public-private mix *x* should be used) and dealing with risks on a meta-basis rather than on a risk-by-risk basis. She admitted that while it would be very difficult to develop this generic approach, it would be very conducive to the discussion of food safety management if our discussions moved in that direction. We need some sort of comprehensive roadmap for managing different classes or risks and knowing which approach(es) to take. Caswell concluded by referring to Taylor's keynote presentation, reminding the audience of Taylor's comments on the need to establish institutional roles and responsibilities. She emphasized that, while considering those roles and responsibilities, we need to think more generically about the private-public mixed mode of regulation and which approaches work best under which risk circumstances.

### OPEN DISCUSSION<sup>8</sup>

The first question was directed to Caswell. Audience participant Sandy Hoffmann of Resources For the Future asked if, in Caswell's generic schematic of mixed private-public roles and responsibilities, a next-step would be to think about the characteristics of the risks or the market system and how those "map into alternative loci of control." Caswell answered yes. While the public health risk associated with any situation is always going to be the guiding principle, other considerations would include market risk, governmental capacity to be effective in that area, the scope and comprehensiveness of private standards and trade impacts.

Ned Groth commented on how the workshop lacked perspective from an exporting developing country (i.e., exporter to the United States) and that it is a very important perspective to consider. At other food safety meetings, developing country representatives often echo concerns about

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<sup>8</sup> This section summarizes the discussion that followed the three presentations of this session.

the “silo effect.” That is, the development of standards and safety systems is often pursued either entirely within the private sector or entirely within the public sector and without adequate consultation with other stakeholders, particularly when those other involved parties are halfway across the world. Government personnel do see each other at Codex, WHO, FAO, or other meetings, Groth noted, where they are able to establish bilateral or multilateral collaborative efforts. Likewise, within the private sector, companies talk to suppliers in other countries, with a lot of one-on-one, back-and-forth interaction within individual problem areas. But how well are we doing at having international discussions where all stakeholders from all countries, both those importing and exporting, developed and developing, are at the table and addressing these issues in an integrated, synthesized way?

Brackett and Caswell both offered responses. First, Brackett agreed that it is an important issue. He noted that while there is communication and shared training between developed country importers and developing country suppliers, there is often a lack of communication between those importers/suppliers and government regulatory agencies. Similarly, academics and government representatives communicate frequently at professional meetings, Codex meetings and elsewhere. But he doesn’t know of any single construct that puts all three sectors—industry, government, and academia—together. That said, some international organizations and private companies currently have proposals in place to do just that, but nothing like it exists yet.

Caswell agreed that it was a very interesting and also very challenging question. The challenge, she said, is that private standards develop very rapidly and are having a significant impact on the market. In fact, one of the “glories of private standards” is that they develop and move rapidly, quickly responding to new and changing situations. In some ways, she said, we don’t want food safety regulation to be in a “Codex mode,” where a meeting occurs but the decision to act on a particular situation doesn’t happen until a few years later. Making the effort to integrate and coordinate public and private parties—and across countries—requires a means of capturing the “dynamic ability of private standards to evolve quickly.” A good intermediate step might be the development of meta-standards, or industry-wide standards. The individual private parties set the standards; those standards give those companies market power.

Mike Robach<sup>9</sup> elaborated on Caswell’s comments on private standards by emphasizing that it is very important when talking about the proliferation of private standards to consider how those standards are sometimes

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<sup>9</sup> Robach, of Cargill Inc., was a panelist in the third session but an audience member during this session.



“forced through the supply chain without appropriate scientific and public vetting.” He noted that Cargill has worked with a number of organizations, including FAO, OIE, and others to standardize its processes and now utilizes these standards in its operation of 850-plus food processing plants in 66 countries, regardless of location. Robach also reiterated that Codex is slow and needs to become “more nimble” and able to adapt to technological change. He suggested that the private sector could facilitate that. Robach echoed the call made by many other workshop participants throughout the day: we need to have all stakeholders at the table—not just inter-governmental agencies and the private sector but also national governments and civil society (i.e., the appropriate consumer input). Not only do all of these stakeholders have a role to play, but their participation also ensures that moving forward is a transparent process.

Another audience participant concurred that standard-setting, while perhaps facilitated by the private sector, should be a public process. She noted the extent to which private industry has been requesting public standards from the government over the years, particularly during times of crisis. A good example is the egg marketing and grading program, which is run through AMS (Agricultural Marketing Service) but was requested by that industry. Likewise with the seafood grading and inspection program run by the National Marine Fisheries Service. Often when industries are in crisis, they turn to government for standards.

Getting back to some of the specifics of Caswell’s talk, another audience member asked to what extent food safety management is really shifting from a “command and control” to a performance or process risk-based system. Or, is the shift from an approach where government issues “command and control” standards to one where the proliferation of private standards has led to a private “command and control” standards? Brackett commented that the movement, at least philosophically, is away from “command and control” to the use of more performance-based standards. He pointed to FDA’s HACCP regulations for juice and eggs as an example: there has been a “log reduction” of what is expected with no expectations of how that is to be accomplished. Utilizing performance-based standards allows industry to be more creative in its approach, he argued. That said, there are still residuals of the old “command and control” system, for example with milk pasteurization, and there are still very specific guidelines about how that must be done. As technology continues to change, however, it is going to push industry even more toward embracing a performance-based approach. Technology is changing too fast to dictate which particular method should be used. Caswell noted that it is in fact possible for the government to be operating in a “performance” mode with companies responding in a “command and control” mode and that these two modes of operation would not be inconsistent.

A couple of technical questions were directed to Flowers. First, a question was asked about his comments about break points and the convention of conducting a sanitation step every third shift in the meat industry: Is it technologically feasible to have extended runs in the meat processing environment, where the potential food safety benefits would be greater than have been realized? The questioner commented that the meat industry has been living with this “dogma” for years and years—that it is appropriate to conduct a complete clean-up on a nightly basis. But is this an area of food safety regulation that needs to be re-addressed? Flowers agreed that in other industries, like the dry food industry, shutting down, cleaning up, and re-starting sometimes creates additional problems and that continuous runs sometimes have fewer microbiological problems. He said it was “possible” that the same might be true of the meat industry and that it would be a matter of verifying (i.e., that your temperature and other post-process contamination control mechanisms are working). However, as Flowers had emphasized in his presentation, he emphasized again that the meat industry relies on data and reacts to data. So while the continuous nature of the dry food runs could be extended to refrigerated plants as well, he said, “I would really have to see that data” before answering that question.

Another audience member asked Flowers about the need for laboratory certification with respect to verification testing. The questioner commented that a number of bills moving in that direction (i.e., requiring lab certification) have been drafted for consideration in the 110th Congress and then asked, are there good international or other models that can be relied on as Congress moves forward on this issue? Flowers clarified that the issue is not certification but accreditation of laboratories and said that, yes, there are good models available, such as the ISO standard for accreditation of laboratories. The issue with those standards, however, is that they are applied to all types of laboratories and are very vague with respect food laboratories. We need much more specific standards. Flowers mentioned a group that he chaired a number of years ago—the Food Laboratory Accreditation Working Group (FLAWG), involving USDA, FDA, and industry members—and how the group wrote some very specific guidelines to accompany ISO Guide 1702-5 with respect to how food laboratories in particular should comply. Flowers also noted that some of the ISO standards, such as a requirement for proficiency testing, have been modified and “watered down” over the years.

Finally, Caswell was asked which policies and changes in regulation over these past two decades have had the greatest impact on reducing food-borne illnesses. Caswell said, “We don’t know.” The questioner commented that it would be a useful research question.



## 4

## The Way Forward: Varying Perspectives

The third and final session of the day, “*Panel Discussion: Where Do We Go From Here?*,” was a four-person panel discussion. Each speaker was asked to provide some insights into the many and varied issues that were raised during the earlier sessions and propose options for moving forward. Moderator Michael Doyle<sup>1</sup> opened the session by introducing Steve Sundlof of the FDA’s Center for Food Safety and Applied Nutrition (CFSAN).

Sundlof noted that the FDA has received the message “loud and clear” that there is a need for more cooperation and coordination between industry and government and that the FDA is truly committed to making this happen within the confines of what its mandate allows. Sundlof described the direction the FDA has been heading over the past year or so with respect to food safety, including the November 2007 launch of its Food Protection Plan, which calls for a range of domestic and international initiatives and activities.

The second panelist was Caroline Smith DeWaal of the Center for Science in the Public Interest. After citing some of the positive developments in the area of food safety that have occurred over the past 10 years, DeWaal described some fundamental differences between how the U.S. federal government’s two food regulatory agencies—the FDA and USDA—approach food safety. She encouraged a move away from both approaches (i.e., the FDA’s enforcement-based approach and the USDA’s recall-based approach) and toward a more unified regulatory structure. DeWaal urged moving

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<sup>1</sup> Michael P. Doyle, PhD, is Regent Professor of Food Microbiology and Director of the Center for Food Safety at the University of Georgia, Athens, GA.

forward even if and when the science is incomplete, which she noted will always be the case. She also commented on the need for more work in the area of risk communication at both the national and international levels.

Mike Robach of Cargill, Inc., spoke after DeWaal, providing an industry perspective on some of the issues. In particular, he argued the importance of recognizing the multitude and range of food systems worldwide and the need to reach consensus on key criteria that impact food safety and public health regardless of where that food is produced, processed, distributed, or consumed. The principles underlying these criteria exist, Robach argued, and are already standardized in multiple ways, from GAPs to HACCP, but food companies, inter-governmental agencies, regulatory agencies, consumer groups, academia have yet to make a concerted effort to harmonize these criteria.

The fourth and final panelist of the session, Richard Raymond, Under Secretary for Food Safety at the USDA, presented a USDA perspective on three issues: (1) risk communication and how USDA's recently established "retail rules" will help alleviate some risk communication problems; (2) how USDA's new information system, which is currently in development, will strengthen the government's capacity to conduct risk-based inspections; and (3) USDA's involvement in a range of international regulatory activities.

A lengthy discussion on several key topics followed the panelist presentations:

- The need to improve communication between industry and government
- The global nature of the food supply chain: challenges and opportunities
- Divergent opinions about the need for more government oversight on farms
- Controversy around the notion of a single unified food agency
- Water quality and waste management: who is responsible?
- Food safety research: some salient topics
- Unanswered questions about food safety trends
- Traceability: room for improvement
- Challenges with microwaveable foods
- The need for an international perspective on the issues addressed during this workshop
- Sustainability and other future food safety issues

## AN FDA PERSPECTIVE ON MOVING FORWARD

*Presenter: Stephen Sundlof<sup>2</sup>*

Sundlof commented on the importance of government and industry cooperation and coordination while moving forward toward establishing a more effective food safety system. It is a familiar theme that has been repeated in many recent meetings involving both government and industry representatives at the national, state, and local levels. The FDA has received the message “loud and clear,” he said, and is truly committed to trying to make it happen within the confines of what government can do.

Sundlof then briefly described the direction that the FDA has taken over the past year or so with respect to food safety. Many recent events, including the *E. coli* outbreak in spinach, the peanut butter outbreak, the melamine issue and, most recently, *Salmonella* in peppers, have forced the FDA to realize that it cannot continue doing things the way it has been doing them in the past; and that the agency needs to make a major shift in how it addresses food safety. In November 2007, FDA launched its Food Protection Plan, based on three core elements, or pillars: prevention, intervention, and response:

1. *Prevention*: This is where the FDA will be putting the greatest emphasis, Sundlof noted. Now, when a food safety incident occurs, FDA typically takes a corrective action. The agency wants to start moving toward a more preventive mode. This aspect of the plan encompasses several initiatives and activities:
  - a. Opening new posts in five geographic areas (India, China, Europe, Latin America, and the Middle East), through FDA’s Beyond Our Borders Initiative and as a way of increasing regulatory presence overseas and ensuring the safety of food imports—not just through inspections but also capacity-building (e.g., making sure our foreign partners understand what is required to meet U.S. standards and providing technical assistance where necessary).
  - b. Building a database of information received from foreign partners about food inspections and food quality (e.g., results of inspections, where problems are detected) and using the database to better target the agency’s inspection and import surveillance programs.

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<sup>2</sup> Stephen F. Sundlof, DVM, PhD, is Director of the FDA Center for Food Safety and Applied Nutrition, College Park, MD.

- c. Strengthening FDA's capacity to collect and interpret data necessary for risk-based prevention, so that the agency can better identify food vulnerabilities and assess food risks.
  - d. Conducting research to improve risk-based prevention strategies.
  - e. Assessing areas of vulnerability (i.e., vulnerability to intentional contamination of food), identifying the most readily available targets that will have the highest impact, and making sure that the food industry is aware of these targets and that they are conducting their own vulnerability assessments.
  - f. Developing and validating rapid detection tools to detect food contamination (e.g., through genetic fingerprinting and the use of other molecular tools) and improving the speed and accuracy of both microbiological and chemical contamination detection (i.e., achieving higher throughput so that test results are provided more quickly during ongoing outbreaks).
2. *Intervention*: This component of the Food Protection Plan relies on targeted risk-based inspections and again encompasses several initiatives and activities:
- a. Conducting testing to verify that preventive controls are in place and are running adequately and inspecting the highest-risk firms on a more frequent basis.
  - b. Hiring additional investigators so that the extent of domestic and particularly foreign inspections could be expanded.
  - c. Developing and using new tools to conduct enhanced risk analysis (i.e., analyses that consider a multitude of factors that contribute to risk, like economic fraud, which was clearly an important risk factor with melamine).
  - d. Improving FDA's ability to integrate and assimilate risk-based information into data systems that allow for early signal detection during contamination problems.
3. *Response*: The goal of this third component of the Food Protection Plan is to improve FDA's response capability. Again, it encompasses a broad range of initiatives and activities:
- a. Reducing the length of time between detecting and containing a foodborne illness.
  - b. Working with various organizations to better understand traceability, identify best practices with respect to traceability, and develop ways to implement those practices (e.g., using the fresh produce industry's own tracing systems to build better ones). For example, FDA will be conducting a workshop in 2009 to review a \$15 million traceability study that has been underway in the European Union since 2007.

- c. Creating a health hazard alert system, to quickly alert the public about outbreaks and illnesses.

### A CONSUMER ADVOCACY PERSPECTIVE ON MOVING FORWARD

*Presenter: Caroline Smith DeWaal<sup>3</sup>*

DeWaal reflected on her participation in an IOM Food and Nutrition Board workshop held in this very room about 10 years ago. The focus of that workshop was on the structure of the U.S. food safety system. She noted that the National Academy's *Ensuring Safe Food: From Production to Consumption* (1998), which stemmed in part from that workshop, added tremendously to the literature and our scientific understanding of the hurdles created by that structure in improving food safety. We have come a long way since then, she said, with many positive developments:

- We have widened our understanding of food safety problems and have moved beyond problem identification and putting tools in place to a point at which we are ready to act.
- Several new coalitions have formed over the past several years with the goal of educating Congress about food safety. One of the most successful of these is the Alliance for a Stronger FDA, where the food industry, consumer groups, the drug and medical device industries, and patient groups have banded together around a single message: that the FDA cannot possibly carry out its mission with its current budget.
- There has been considerable development around the concept of risk assessment; and we have seen the formal development and even impartial implementation of an international risk analysis framework.
- With respect to risk management, in the United States, there has been a rise in the use of microbial risk assessments and adoption of HACCP. The USDA, for example, has adopted HACCP for its entire regulatory industry. FDA, on the other hand, utilizes HACCP only for seafood and juice products, relying on a commodity-by-commodity approach elsewhere.

DeWaal expanded on this last bullet point, noting that adoption of HACCP by the USDA versus the commodity-by-commodity, or crisis-by-

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<sup>3</sup> Ms. Caroline Smith DeWaal is Director of the Food Safety Program at the Center for Science in the Public Interest, Washington, DC.



crisis, approach of the FDA reflects important and fundamental differences in the regulatory approaches of these two agencies.

The FDA follows an “enforcement model.” A great example of this, she explained, was when Commissioner David Kessler<sup>4</sup> seized processed orange juice because it was labeled “fresh,” with little or no warning to the industry. He simply enforced the law. Still today, the Office of Regulatory Affairs (i.e., the inspection arm of the FDA, as opposed to the policy-setting arm) conducts their inspections by developing evidence in order to bring action. While that action might be only a warning letter, their level of review and analysis is such that the action would be supported in a court of law if necessary. They follow a very high standard. A shortcoming with that approach, however, is that because FDA inspectors are not in the food plants very often, they are not looking for systematic problems and are not necessarily finding solutions. They are largely enforcing the law, in accordance with their statutory framework (i.e., the enforcement-based Federal Food Drug and Cosmetic Act).

USDA, on the other hand, relies on somewhat newer “recall model,” whereby a high-level regulatory official declares “zero tolerance” for high-risk pathogens or other ingredients and then, when violations in the law are detected, recalls are issued. While these are largely voluntary recalls, the industry largely complies. The recalls can be massive and can extend to products with very, very low relative risks, with the goal being to remove all contaminated or potentially contaminated product from the market. While an enforcement action linked to that recall may follow, the focus usually remains on removal of the contaminated product from the market.

DeWaal then offered advice to the next administration (i.e., the Obama administration): “To take us away from what we’ve got today, with all its warts and problems, into a modern food safety structure.” She called for a unified structure with unified food laws (both the 1906 and 1957 laws are antiquated, she said) and a move away from both the enforcement model (FDA’s current approach) and the recall model (USDA’s current approach). While both of those approaches could be used as last resorts, they should not be the first regulatory step taken when problems arise.

DeWaal also called for the next administration to develop policies that would put the United States into an international consumer leadership position. While we already play an important role at Codex meetings, DeWaal would like that role to be only part of the U.S. leadership role with respect to consumer protection. For example, she would like to see greater expertise applied to the important role of risk communication, so that risk communication triggers the appropriate consumer responses. Just over the past year, we have had massive recalls and many examples

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<sup>4</sup> Kessler was Commissioner from November 18, 1990, to February 28, 1997.

of risk communication at work. The reality is that many people do not always respond appropriately and, at a certain point, many consumers simply get tired of the messages and stop paying attention altogether. So, while risk assessment and risk management have both received a lot of attention and are both moving forward, risk communication has not received the same level of attention at either the national or international level. It is time.

Finally, DeWaal commented on Caswell's notion of developing a generic joint public-private approach toward food-safety risk management. Importantly, DeWaal emphasized, any structure we devise has to be based on imperfect science because "we are always going to be operating with imperfect science." Doing nothing because the science is incomplete (e.g., not appropriately responding to a foodborne illness outbreak because we are not sure how the pathogen entered the food supply) is unacceptable and "not good consumer protection."

## AN INDUSTRY PERSPECTIVE ON MOVING FORWARD

*Presenter: Michael Robach<sup>5</sup>*

Robach reiterated DeWaal's comment that we have learned a lot about food safety over the past 10-15 years. He commented, however, that we would be learning even more if we could effectively share our collective experiences and use those as a basis for moving forward. Too often we reinvent the wheel when solutions to particular problems may already exist, he said, if not here in the United States then in other parts of the world. Robach argued that: We need to take a step back and get a global view of the wide range of existing food systems, from Natural Selection Foods' organic system (which Daniels described earlier in the workshop) to Cargill's worldwide operations. Importantly, while Cargill conducts business around the world (in 66 countries) many of its businesses are focused on local marketplaces. In Central America, for example, products from poultry and meat processing and feed operations are sold locally. Others, like the large operations in Brazil and throughout North America, export worldwide. So even within this one company, there are many different food systems. We must be cognizant of this range of food systems in our efforts to achieve better food safety. The same system that works in one place, for example in the United States, does not necessarily work in, say, Paraguay or Indonesia.

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<sup>5</sup> Mr. Michael C. Robach is Vice President of Corporate Food Safety and Regulatory Affairs for Cargill, Inc., Minneapolis, MN.

- We need to more effectively take into account our entire supply chain, linking what is happening on the farm, whether in agriculture or animal husbandry, with what is happening inside the processing plant (i.e., during production and packaging) and with what is happening after a product leaves the process plant (i.e., during distribution and consumption).
- We need to reach consensus on key criteria that impact food safety and public health regardless of where that food is produced, processed, distributed or consumed.

Robach elaborated on the last point, arguing that in fact these criteria already exist and are already being utilized but not in a harmonized, consistent way. For example, we have GAPs and other (botanical) plant-related criteria established by the International Plant Protection Convention (IPPC), all of which were vetted and agreed upon. Likewise, we know what the right criteria are for good animal handling practices (i.e., through the work of the World Organization for Animal Health, or OIE), and we have an established set of principles for good hygiene (i.e., through Codex) and, in many places, GMPs. Similarly, the principles of HACCP were vetted through Codex, as well as through the National Advisory Committee on Microbiological Criteria for Food. We also have a standardized risk- and science-based hazard analysis, including an understanding of what the likely hazards are, where they will likely enter the process and what control measures can and should be put into place. So these principles exist. Now, we just need all stakeholders at the table making an effort to position these standards and ensure that our supply chain is safe. Food companies around the world need to work together with national governments, inter-governmental organizations (i.e., FAO, Codex, WHO, OIE), regulatory agencies, consumer groups, and academia to assemble food safety programs operating against the same set of principles, or criteria, and with the available technologies. The process needs to be transparent, and it needs to stay focused on the desired outcome: to have safe food around the world.

Robach commented on the proliferation of private audits, arguing that they are conducted primarily out of frustration and because of the disharmony that exists around the international regulatory infrastructure. For example, it is very difficult to be working in a poultry plant in Brazil while trying to meet the regulatory requirements of seven different countries with the same product. We need to improve that way of conducting business. Over the next 40 years, we will be going from six-plus billion people to nine billion. We are going to have a lot more mouths to feed, and we will need to be a lot more efficient and smarter with food production.

Finally, Robach expressed the need to adopt a more global mindset and recognize that there are no “bad” countries with respect to food safety. For

example, while China has received a lot of negative attention, in fact there are some really good processing plants in China that do outstanding jobs. Likewise in the United States—there are good and bad plants. Instead of looking at country-level food systems, we need to think of the food supply chain as the global food system.

Robach also stated that the industry needs more holistically trained individuals. Too often, new college graduates focus on animal nutrition, food microbiology or some other discipline and are not seeing the whole picture with respect to the way the different components of the supply chain are linked together.

## A USDA PERSPECTIVE ON MOVING FORWARD

*Presenter: Richard Raymond<sup>6</sup>*

Raymond began by echoing other comments on the international nature of the food supply chain, pointing to ground hamburger as an example: you don't know whether the ground beef you are eating came from Uruguay, New Zealand, Australia, Canada, or elsewhere. Then, he remarked on three specific issues from a USDA perspective: risk communication, the use of risk-based USDA inspections in the future, and USDA's role in ensuring a safe *global* food supply:

1. *Risk communication.* Raymond remarked that the “retail rules” passed and published in July 2008, which now allow USDA to notify consumers which stores sold recalled products, will be a tremendous boost for the consuming public and will help alleviate some risk communication problems. Raymond agreed with DeWaal that risk communication is still a major problem and that there needs to be a better way of teaching people how, for example, to use thermometers when they cook poultry, ground beef or other USDA-regulated products. He noted that improving risk communication is not, however, just a matter of getting more information out there. It is also a matter of removing the “bad” information that is already out there and dispelling rumors that feed misinformation.
2. *Risk-based inspections of the future.* Raymond briefly described a new “21st century” database under development that he said is “short of fantastic.” With the press of a button and within a few seconds, answers can be retrieved regarding, for example,

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<sup>6</sup> Richard Raymond, MD, was appointed Under Secretary for Food Safety at the USDA's Food Safety and Inspection Service in 2005.

which plant(s) has the highest risk of being responsible for a food borne disease outbreak based on pathogen testing conducted over the past two years. The database is not operational yet. It will be launched in the third quarter of 2009. When fully operational, it will make USDA “nimble and quicker,” he said, giving the agency the capacity to not only respond more quickly to recalls but also prevent recalls through predictive analysis. USDA has organized a new group, DAIG (Data Analysis Integration Group), which along with the Data Coordinating Council (comprised of members from all parts of the FSIS), will determine how to coordinate and make best use of the data.

3. Raymond explained how a past Freedom of Information Act request cost thousands of person-hours. You couldn’t just search “tongue” or “tongil,” for example, you had to search all of the different possible spellings (or misspellings) of each word. This new information system will not only alleviate some of this type of data-mining frustration, it will also allow for risk-based inspections of both processing and, eventually, slaughter plants. Right now, as bound by law, USDA spends exactly the same amount of time inspecting a ground beef plant as it does a plant that processes chicken noodle soup. This is true despite the fact that the former have involved more recalls and suspended inspections. You just don’t see children dying from eating vegetable-beef soup, Raymond said, but you do see children dying from eating contaminated meats. Yet, USDA is not allowed to conduct different levels of inspection among these different types of plants; at least not yet. USDA’s new information system will allow for a risk-based inspection system not possible until now.
4. *The international nature of the food supply.* By law, every exporting country must have an equivalent food-safety system for meat and poultry products shipped to the United States. There are several steps that must be taken to determine equivalency. First, USDA conducts a paper audit to ensure that the country has the rules, regulations, policies, and finances in place, such as the daily presence of federal inspectors in continuous processing and slaughter plants, etc. If on paper, a country has an equivalent food safety system USDA conducts on-site inspections of selected establishments, laboratories, etc. If based on those on-site inspections, USDA determines that the country has an equivalent food safety system in place; then the lengthy rule-making process can begin. After that initial audit, USDA conducts yearly audits and on-site inspections to ensure that equivalency is being maintained. Also 10 percent of all import boxes are opened and the shipped products

themselves are inspected, and 5 percent are sampled for pathogens and chemical residues.

To date, the USDA has determined that 34 countries have equivalent food-safety systems for meat and poultry. Only 29 of those countries currently export to the United States. The other 5 do not export primarily for economic but also other reasons. Compared to what the FDA must manage, Raymond said that 29 are “pretty easy.” But, there are some vague areas and issues that USDA is still contending, for example how to define equivalency and which is more important: inspecting processing or inspecting the final product (i.e., whether it is more important to conduct on-site inspections of processing or slaughter plants and determine whether tests for *E. coli* in Australia, for example, are comparable to tests for *E. coli* in the United States *or* inspect products after they have been shipped by opening and sampling boxes). And should countries with perfect records (e.g., a country that has never had problems with mislabeling, damaged products, or pathogen issues upon sampling of import boxes) be audited just as frequently as countries that have had problems (e.g., a country that has been de-listed twice in the last three years)? International inspections and equivalency-testing need to be just as risk-based as domestic food safety considerations, he said.

## Open Discussion<sup>7</sup>

### *Improving Communication Between Industry and Government*

The discussion started with a question by Doyle about communication between industry and government. Given that so many speakers today had recognized the importance of more open and frequent communication between industry and government with respect to food safety, Doyle asked, how can this be achieved? Usually when the FDA and industry meet to discuss food safety, it is during an outbreak situation or in regards to a particular inspection. Is there a way to facilitate a regular dialogue?

Sundlof was the first to respond. He noted that much of the lack of communication is “cultural.” Even among the various regulatory agencies, there is a tendency not to share information. The CDC, for example, works very closely with state-level agencies and is sometimes reluctant to share that state-level information with the FDA in order to avoid having particular states implicated in outbreak situations. The FDA in turn, is often reluctant to share information, which if released, would be harmful

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<sup>7</sup> This section is a paraphrased summary of the lengthy discussion that followed the panelists’ comments.

to industry. We need to create a culture where information is shared more openly while also being cognizant of the fact that some of that information could be harmful and needs to be protected to the extent possible. To that end, the FDA is currently seeking legal solutions to some of the current problems with the Federal Advisory Committee Act (FACA). As an illustration of those problems, at a recent meeting with executives from the produce industry, the FDA could not ask advice or seek consensus because of FACA and was limited to going around the room and asking the attendees to simply share their experiences. Having a mechanism in place to allow for more information sharing would help the FDA help industry.

Raymond agreed that there needs to be more open and regular communication among the regulatory authorities, industry, and consumers. He noted that the USDA meets with industry representatives and consumers on a monthly basis and, in fact, to the extent that sometimes questions are raised about “how cozy” the relationship is given USDA’s regulatory role.

Robach agreed that there must be more communication between industry and government. He relayed the story of a ground beef recall in October of 2008 and the lack of communication between the USDA, public health authorities, and industry. The recall was because of an *E. coli* O157:H7 illness, which had occurred in Minnesota but was associated with product coming from a Cargill plant in Wisconsin. Robach didn’t even know that the Cargill plant had been implicated until he received a call from the Wisconsin plant informing him that some USDA compliance officers were at the door. That phone call, in turn, prompted Robach to call the Minnesota Departments of Health and Agriculture. Coincidentally, when he made those calls, both agencies were in the middle of a conference call discussing the outbreak and a potential recall. It was “maddening and frustrating” not to have been notified or included in that conference call, Robach said. He urged more open communication, admitting that sometimes industry may push back. More often than not, however, “people are going to really roll up their sleeves and find out what the issue is.” When that *E. coli* O157:H7 illness was traced to a product processed in Cargill’s Wisconsin plant, that product was off the market that afternoon. Communication needs to begin early on, Robach emphasized, at the first hint of a problem and when the collective use of both government and industry resources can be leveraged to offer the best protection possible for public health—not after the regulatory agency has already crossed all its Ts and dotted all its Is.

DeWaal noted that while much of the discussion has been focused on the need for more communication between government and industry, the FDA also needs to improve its risk communication with the consumer community. The USDA has done a good job at keeping consumers informed about food safety policy and has made efforts to improve risk communication, she said. Noting that the FDA has far fewer personnel available to



work on communication, DeWaal encouraged the FDA to “work harder” with respect to communicating with the consumer population—both with respect to food safety policy and crisis communication.

### *The Global Nature of the Food Supply Chain*

Doyle identified another common theme throughout much of the day’s discussion: the rapid increase in food imports and the global nature of the food supply chain. He asked how the FDA was addressing issues around unsanitary practices currently used in many foreign countries, such as the use of raw human sewage in agricultural irrigation and the use of untreated animal manure in tilapia and shrimp ponds. These practices are at the root of many of the food contamination issues here in the United States, he argued.

Sundlof replied that the FDA obviously strongly advocates GAPs and, in many outbreak situations, has provided technical assistance to other countries in an effort to establish GAPs. This includes everything from teaching farmers how to conduct environmental sampling to teaching them to recognize the importance of have sanitary conditions for their workers. He noted the existence of international third parties that conduct GAP inspections. These efforts aside, Sundlof agreed that is an issue that needs to be addressed more fully, especially now that we are seeing new types of outbreaks (e.g., *Salmonella* in peppers, which has never occurred before). But it is a monumental problem and one that will require an international, not just FDA, solution. While the USDA has identified 34 food safety equivalent countries, of which 29 export to the United States, the FDA deals with 150 countries—that is the majority of the 190-plus countries that exist. Conditions are highly variable among countries even with the same commodity, which makes the development of comprehensive standards applicable to all countries extremely complex and difficult.

Robach agreed that the problem is not one that the U.S. government will be able to solve by itself. They do not have the resources, nor should they be expected to be responsible for solving this problem. Robach reiterated that the private sector is ultimately responsible for the safety of its supply chain. Cargill, for example, assumes responsibility for assuring the origination of products entering its processing plants. Still, the private sector needs to partner with inter-governmental organizations and national governments so that standard, appropriate criteria can be developed. There are many good examples of well-vetted, consistent supply chains, with most companies having assembled them for their own use. He argued that the criteria for standards exist—now, the private and public sectors need to sit down and agree that these criteria exist so that we can move forward. While Robach warned not to “go overboard and start imposing our western ideals



on developing countries,” he emphasized that there are some essential elements of food safety that need to be employed by all countries participating in the global marketplace.

Raymond identified two ways that U.S. federal government efforts have impacted the global food supply chain by decreasing the proportion of U.S. imports of products not processed according to GAPs. First, since the summer of 2005, four countries have stopped exporting to the United States because of USDA audits. Second, former President Bush chartered an interagency Working Group on Import Safety in July 2007. Represented by 12 departments and/or agencies in the federal government, the group developed a comprehensive plan not just for the safety of food imports but also for the safety of all imports. Because of this plan, we have seen a tremendous increase in the number of seized illegal products that would otherwise have entered the United States.

DeWaal agreed that the issue is an important one and one that deserves Congressional attention. She emphasized, again, the reality that the United States has two entirely different regulatory systems functioning (i.e., the recall system of the USDA and the enforcement system of the FDA) and different levels of confidence built into each (i.e., USDA checks and reviews all imports, whereas FDA relies on a take-all-commerce approach). She mentioned that CSPI started looking at this exact issue—the safety of incoming products—a number of years ago but did not come up with very satisfying answers. Part of the challenge stems from the reality that there is no border checkpoint that can be used to ensure the safety of imported products; which means that you must go to the country of origin and ensure that their food safety system is functioning. To that end, CSPI has worked with WHO, FAO, and about 25 other consumer organizations to develop guidelines for engaging NGOs in source countries in the effort to ensure food safety of those countries’ domestic programs. If their domestic programs are improved, DeWaal explained, their export programs would improve as well. While these efforts are not an entire solution, they are the beginning of “bootstrapping” food safety on a global level. DeWaal pointed to other efforts by the World Bank but noted that most of those efforts are “stove pipe” efforts that fail to benefit consumers of the source country. For example, if a country is having problems with its fish exports, the World Bank will build a fish export program to ensure safe products for export but without benefiting consumers in the source country. DeWaal also encouraged workshop participants to visit [www.safefoodinternational.org](http://www.safefoodinternational.org), where international outbreaks are tracked.

*More Government Oversight on Farms?*

Doyle asked the panel whether we need more government oversight on farms, given the importance of producing food under sanitary conditions and the problems that arise around that issue.

DeWaal responded first. “Absolutely,” she said. “We need more oversight on the farm.” As with all food safety programs, however, that oversight should begin with a written plan and should be within the farmer’s control. In fact, she argued, most farmers have effective food safety systems in place. Otherwise, more of what we are eating would be making us sick. Most of what we eat does not make us sick. So clearly something is working. However farmers should be able to document the effectiveness of their programs (e.g., their water quality, fertilizer inputs, and farm worker sanitation programs), and those programs should be capable of being audited. There should be government-set standards (i.e., FDA standards) regarding what the plans should entail. As with the processing and slaughter plants, food safety begins with industry and, as such, government oversight should be a function of audit, review, and discussion (e.g., informing farmers that their hazard analysis is incomplete or that their safety plan needs to be improved). Only in instances where the farmer does not implement their plan or otherwise meet federal requirements would governmental oversight become enforcement. The CSPI has petitioned the FDA for such a program. She urged the FDA to take action on this petition.

Doyle then offered his own opinion on the matter and said, “No, we don’t need more governmental oversight on the farm.” Having inspectors on farms is not really going to improve food safety. Rather, we need the private sector to be more diligent when building its food safety systems. This includes developing a mechanism for data sharing in the event that a regulatory agency needs that information. Doyle reiterated what Robach had argued both during his presentation and in response to the previous question about the global nature of the food supply chain: that we need to take a step back and re-evaluate our criteria for safe food production, distribution, and consumption and then make sure that those criteria are being employed. Verification and validation that those criteria are being met must be a transparent process and the information shared in a way that builds confidence in the safety of our food supply.

*Do We Need a Single Unified Food Agency?: Contrasting Opinions*

Elsewhere during the panel discussion, while urging FDA to “work harder” with respect to risk communication, DeWaal had referred to her dream of a single unified food agency.” This prompted Doug Podolsky

of *Consumer Reports* to ask the panel to discuss this dream, or future solution.

Raymond was adamant that he did not share this vision. Rather, his “dream” was that policy makers meet with industry food-safety experts, consumers and scientists to identify the riskiest food products consumed in this country, where those products come from and discuss what should be done to increase their safety. He argued that a single food safety agency will not be able to do anything unless the laws change, as the USDA is bound by a set of very prescriptive laws, the FDA much less so. These legal problems are compounded by financial problems. If you were to combine the food safety components of the FDA and USDA into a single agency and provide them with the same amount of total funding they each have today, Raymond argued, the consequences would include no longer having continuous inspections of slaughter plants because some of the money currently being applied toward that aspect of USDA’s food safety program would be re-directed toward FDA activities. Right now, both the USDA and FDA do the best they can with the funds they have and the laws and statutes that mandate their actions. A single food agency cannot rectify these problems. Instead, we need to spend our time and energy on solving the legal and financial problems that already exist within each individual agency. For example, the law does not allow risk-based inspections: Not only does a ground beef plant receive the same level of inspection as a chicken noodle soup plant; tomato soup plants receive no inspections. This is despite the fact that not only is the risk much greater in the ground beef plant than it is in the chicken noodle soup plant, but there is probably very little difference in risk between a chicken noodle soup and a tomato soup plant. That is where we will be most productive, Raymond said, fixing that type of problem.

Sundlof agreed with Raymond. He said that the notion of a unified food safety system is a “noble idea” but that the amount of work that would be required to harmonize the two systems and re-write the laws and regulations of a new unified agency is daunting. If the United States were just at the beginning stages of developing a food safety system, then yes, it would be a valid idea. But not now.

DeWaal referred workshop participants to the IOM/NRC *Ensuring Safe Food: From Production to Consumption* report and remarked that, in fact, the notion of a single unified food safety agency is very much a topic of discussion in the 110th Congress. She mentioned efforts by the chairwoman of the Agricultural Appropriations Committee (Rosa DeLauro), who manages both the CFSAN and FDA budgets, and the efforts of Dick Durbin, Democratic Whip in the Senate and a key congressional legislator. There are many bills currently under consideration that would bring us closer to this vision of a unified agency, she said. It will be a step-wise effort, with

most of the early efforts being directed to toward making improvements at the FDA because of the critical condition of that agency.

A member of the audience who identified himself as a local inspector who visits many different types of plants, including both FDA and USDA facilities, said that originally he was ambivalent about this notion of a single agency (i.e., nine years ago, when he started conducting these inspections). But now, after nine years of dealing with recalls, trace backs, detentions and other issues, he has realized that a single agency is in fact very important as a means of ensuring that the focus on food safety be retained and that decisions and actions around food safety not be impacted by political motivations.

Another audience member, Donna Rosenbaum, Executive Director of S.T.O.P. (Safe Tables Our Priority), commented on the fact that S.T.O.P. has been attending food safety meetings such as this one for a very long time and still finds many of the same issues (e.g., safety along the entire farm-to-fork continuum) discussed but unaddressed. She wondered if perhaps part of the inaction is because of agency focus and the fact that each agency is overseeing only its portion of the food safety system(s). No single agency is wrapping their arms around some of these very important issues, such as water quality and animal waste management. She asked, how would a single food safety agency be able to deal with these two issues in particular? Rather than addressing this specific question, the discussion turned toward the current regulatory and research status of these two issues.

### *Water Quality and Waste Management*

Robach said that, from a processing standpoint, water quality is an extremely important issue. Water is obviously a key input into all food production processes, and Cargill treats water as a critical ingredient and evaluates it the same way it does any other product ingredient. Cargill assumes responsibility to demonstrate that the water it uses during food production meets drinking water standards, and USDA has access to those verification and validation records if necessary. Cargill also works closely with public water supply sources, as water is already fairly well-regulated at the state level. He argued that he is not sure how government would be able to contribute to that effort; likewise with animal waste management. Cargill works with state environmental protection agencies with respect to waste utilization, methane recycling, composting, and disposal issues, clean air standards, etc., all of which are again fairly well regulated (i.e., at the state, not federal level). There is already enough government oversight, he insisted.

Rosenbaum commented that state-level regulation of water is actually problematic since it contributes to varying water qualities. Sometimes the

quality of the water used in irrigation is not the same as the quality of water being used to wash plants in the packing houses. In California, for example, tertiary water is sometimes used for plant irrigation. She asked, isn't this a problem?

Sundlof agreed that, absolutely, the use of tertiary water is problematic. FDA's GAP guidance deals specifically with the issue of water quality (e.g., that the water being used for irrigation or processing is not transmitting pathogens) as well as worker sanitation (e.g., that workers have access to port-a-potties, hand washing stations, and other sanitation tools and are not the cause of the problem). While that guidance is not law, FDA does have the statutory authority to require that food is produced under conditions that will render it not injurious to health, to identify problems with water quality and to take regulatory actions when those problems arise. As one example of FDA's role in this area, after identifying a *Salmonella* problem in cantaloupe imported from Honduras, FDA conducted on-site inspections on the implicated cantaloupe farms and found many violations. There were problems with both water quality and biosecurity (e.g., birds roosting in areas where cantaloupe was processed). Because of these problems, Honduras is on import alert right now and will not be allowed to ship cantaloupe to the United States until they have improved their production system to a point at which we believe they can produce safe cantaloupe.

Bruhn noted that both issues (i.e., water quality and waste management) were the subjects of active areas of research. At the University of California, Davis, for example, a scientist in the School of Veterinary Medicine is funded by a major grant to examine and identify sources of contamination in aquifers. Other researchers are examining the various ways that composting can lead to sufficient heat generation (i.e., as a way to destroy microbes).

### *Food Safety Research*

While on the subject of research, Bruhn also commented on the fact that most food safety research is conducted in the United States because of the constraints of the funding agency(-ies). This is true even though research conducted elsewhere might be pertinent in this country.

Bruhn also expressed frustration that a recent Request for Proposal (RFP) for research relating to consumer safe handling excluded consumer research (e.g., the type of research that Bruhn conducts) because it would involve human subject research. While Bruhn agrees that there is a need for laboratory research, which was the focus of this particular RFP, there is also a need to understand how people behave (e.g., that they eat raw dough) and what can be done to change that behavior.

*Lessons Learned: Room for Improvement*

Rosenbaum commented on the fact that upwards of 90 percent or more of food borne illnesses are sporadic cases, not outbreak situations, and by focusing on outbreaks we are failing to understand the greater majority of food borne disease. This was followed by a related comment by S.T.O.P. president and spokesperson Nancy Donley. Donley remarked that after closely following food safety issues for 15 years, ever since the Jack-in-the-Box epidemic really catapulted the issue of food safety into the public eye, despite new technologies and other innovations and new research, and new money allocated to agencies for food safety projects, food borne illnesses still occur and people still die from them. Why? Where have we gone wrong?

Raymond replied that improvements could be made in almost any area of food safety that has been discussed today. The complexity of the issue makes it very difficult to pinpoint any single most important problem area. It is an extremely difficult question to answer. Raymond agreed with Rosenbaum that we don't understand most food borne illnesses and that, until we do, it is going to be difficult to make many dramatic changes. That said, there have been some significant improvements. For example, *Salmonella* numbers in poultry have gone down, although whether or not that translates into a decrease in *Salmonella* infections in people who eat poultry remains to be seen.

Raymond also noted that some of the trends, for example with *E. coli* O157, with the numbers getting worse, could be a result of improved surveillance and not an actual increased risk. With PFGE and other advanced technologies, we might be detecting outbreaks that may not have been identified as outbreaks in the past. Or, more people might be seeking medical care than in the past because they read about *E. coli* in the paper or otherwise are aware of the problem. So are we getting better at detecting contamination, or is the contamination getting worse? It could be either or both, he said. Raymond also noted that the USDA is currently considering several changes, which if approved, will hopefully lead to additional improvements in the next few years, such as the use of low-dose irradiation of beef carcasses to kill *E. coli* O157:H7.

Sundlof said that he too wished he had an answer. The FDA was encouraged by the drop in food borne outbreaks of *Salmonella*, *E. coli* O157:H7, *Campylobacter*, and other pathogens detected after initiating a tracking program in the mid-1990s (as part of the HHS *Healthy People 2000* initiative). The agency set higher goals for *Healthy People 2010*. Some of the numbers have gone down, but the FDA has been very disappointed with the worsening trends for many foodborne pathogens. He said that the FDA asks itself this same question: Why? For example, are these microbes

more capable of thriving in the open environment than in the past? Have they evolved the capacity to contaminate foods that they were not able to contaminate in the past? Or has our surveillance improved, and are we simply detecting outbreaks that we missed in the past?

Bruhn argued that perhaps part of the answer is to be open toward new technologies and to communicate the risks and benefits of these technologies to the public. For example, with respect to the issue of irradiation, Bruhn commented on how research in the past demonstrated that irradiating leafy greens wilted them. Now, with technological advances, irradiation can result in a “two to three log reduction, at least” and products that are indistinguishable from non-irradiated products both, in terms of nutritional value as well as texture. She noted a 2001 publication in *Emerging Infectious Diseases* by Robert Tauxe,<sup>8</sup> where Tauxe argued that if half of all ground beef, poultry, and processed meats were irradiated, over 350 lives would be saved every year and more than 6,000 serious foodborne illnesses averted.

DeWaal remarked that FDA has approved irradiation of spinach and lettuce, which marks a step forward in improving food safety for leafy greens.

Groth agreed that FDA approval of irradiation for leafy greens is an important step forward but emphasized that irradiation is not a “silver bullet.” It is still unclear whether the technology will serve as a practical tool for solving various problems. Most of the work to date has been in the laboratory, leaving many unanswered questions about commercial production; and whether and how the technology can be fine-tuned to be effective against specific pathogens on specific substrates. Groth noted that it is unclear whether even a two- or three-log reduction is sufficient to meet the safety objectives of both producers and consumers given the way these products are handled after processing. There is still a lot more work to be done, and it will probably be a few more years before we see a market for irradiated leafy vegetables.

### *Traceability*

Caswell asked the panel about the quality of traceability in the United States. She said that she was really struck by press reports about traceability in tomatoes and stories about how tough it is to tell where tomatoes originate, as though it is impossible to do that. Likewise with ground beef. She asked, how much would traceability cost relative to the benefits? And

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<sup>8</sup> Tauxe, R. V. 2001. Food safety and irradiation: Protecting the public from foodborne infections. *Emerging Infectious Diseases* 7(3 Suppl):516-521.



is the United States falling behind other developed nations with respect to traceability? If so, how can we improve our traceability capacity?

Raymond commented that, obviously, the USDA does as much traceability as it can to determine contamination sources. This can be especially difficult with ground beef in particular, given that grinders mix and match products not only from different slaughterhouses but from different countries (i.e., trim from the United States is blended with trim from other countries in order to make a leaner burger). The Topps recall, for example, involved 12 sources, making traceback very difficult. Fortunately, in that outbreak, contaminated product was also identified in another plant involving only one supplier (i.e., one of Topps's 12 suppliers), giving USDA the information they needed to trace the contamination back to that single slaughter plant. Otherwise, with multiple suppliers, it is a very difficult exercise. USDA is encouraging industry to hold all product that is tested before it is distributed. Most of the larger companies are now doing this, so there has been some progress. But it is more difficult for smaller companies. Another indication of progress, Raymond pointed out, is USDA's "Steps Program," whereby multiple suppliers to a single processing plant are entered into the program and, if identified twice within a certain time period as being a possible source of contamination, they are required to undergo testing at an increased frequency.

DeWaal answered, "With respect to animal identification, we are way behind." She commented that, because of the BSE crisis, the European Union now has a very extensive animal ID system in place. In fact, most countries trading in the world market have extensive animal ID systems in place, since they must verify that animals entering EU markets have not been treated with hormones. With respect to tomatoes and other produce, DeWaal suggested that the stickers currently being used for check-out purposes at the supermarket could also be used as a way to track those food items back to the farm. In fact, the U.S. Congress passed a law in 1930, the Perishable Agricultural Commodities Act (PACA), requiring that farmers be able to trace their products from the farm to their first distribution point [one must have a PACA license in order to operate a produce business]. There is also the 2002 Bioterrorism Act, which requires that traceability subsequent to distribution. So a tomato distribution plant, for example, can identify where their tomatoes came from (as per PACA) and where they go (as per the Bioterrorism Act) but not necessarily what happens to those tomatoes while in the distribution plant. In other words, there is no internal traceability, and the identity of those tomatoes is lost. We need to examine both external and internal traceability, she argued. Again, in Europe, meat-processing plants have both good external and internal traceability, so it can be achieved. If you were to go to a veal plant in the Netherlands, for example, you would be able to identify not only where every calf was raised



but also where every piece of meat from a single animal was shipped and what grain products were used to feed that animal.

Sundlof agreed that traceability is possible. But is it feasible? He mentioned that there are sophisticated technological solutions to some of these problems in the works but that tomatoes present a worst-case scenario. Tomatoes from multiple farms are combined and then sorted by size and color in the processing plant; so there is a lot of co-mingling of tomatoes from different farms. Then, that co-mingled group of tomatoes may be sent to another distributor and combined and then sorted again. Then, products co-mingle again during restaurant distribution, with distributors selling and buying back products from “jobbers,” etc. In order to sticker-mark a tomato for traceability purposes, he said, you would have to apply a sticker at every step along the supply chain and could conceivably end up with a tomato completely covered by stickers. Again, there are some technological solutions being developed and tried, for example, the use of lasers to etch bar codes into produce, but it remains to be seen how well these will work.

Robach remarked that animal identification (ID)/traceability is not a major issue in the vertically integrated poultry and hog industries. It is, however, a problem with the beef industry, not just because of the way that beef animals are raised (e.g., being sold multiple times before reaching a feedlot) but also because there is no premise ID program in the United States.

### *Microwaveable Foods: Challenges and Changes*

Doyle asked the panel about microwaveable foods and mentioned the recent *E. coli* O157:H7 outbreak associated with microwaveable pizza and the *Salmonella* outbreak traced back to microwaveable pot pies. He noted problems with the way microwave units are sold, such as the fact that they are not all the same wattage and do not cook at the same level, etc. Also, consumers often have different expectations about whether these products need to be actually cooked versus just heated. Do these types of foods need to be free of harmful bacteria, or should they be ready-to-eat with the onus on the consumer to make sure that he or she cooks the products sufficiently to kill *E. coli* and *Salmonella*?

Raymond responded by saying that all food should be free of pathogenic bacteria, even raw poultry. In reference to the *Salmonella* outbreak that was traced back to pot pies, he noted that in fact a lot of people did not cook the pies correctly. He noted the typically low wattage of microwaves in, for example, college dorm rooms and the reality that most people do not leave their microwaveable products in the microwave as per many product cooking instructions (e.g., cook on “high” for four minutes and then leave

in the microwave for two minutes). He asked, why don't companies instruct their consumers to simply cook it for the necessary time (i.e., without requiring that the cooked food sit before eating)? In fact, industry is working on this issue, trying to make their instructions easier to understand and less variable. Raymond also noted that some people like the raw dough of pot pies and will eat that dough and only microwave the rest of the contents. So there are a lot of consumer behavior issues that need to be considered. Finally, he noted that there were some problems with the epidemiology investigation surrounding that outbreak and that the initial assumption was that chicken pot pies were to blame; more specifically, that chicken was to blame, not the flour, even though flour could have been the problem. So the USDA received all of the initial blame, with FDA "off the hook."

Sundlof noted that the FDA is currently dealing with similar issues: that products not labeled as ready-to-eat and with a cooking step are not always being appropriately prepared (cooked) by the consumer. For example, frozen peas and other vegetables meant to be cooked often end up in salads or salad bars without having had a kill step applied to them. This happens even though the labeling clearly states that the products should be cooked before consumption. Should we reclassify these foods as ready-to-eat foods and require a kill step during processing? The problem with that approach, he said, is that people like eating foods that they consider fresh.

Doyle added that raw products with grill marks (i.e., raw products that look like they have been cooked) can be problematic. He noted a recall of grill-marked raw chicken because of *Salmonella* contamination and the fact that the labeling did not caution consumers that the product was raw.

### *Gaining an International Perspective*

Groth commented again on the lack of a developing country perspective in this workshop. He mentioned an upcoming food production meeting in Beijing, China, where food safety would be featured prominently. He also mentioned a meeting that was held earlier in the summer, in Europe, where about half of those in attendance were from exporting developing countries. He suggested that a similar meeting be held in the United States, where industry, government agencies, and civil society representatives from the United States and other importing countries meet with representatives from major exporting developing countries. Groth asked the panel if such a meeting would be useful and, if so, who would sponsor it.

Sundlof agreed that the European meeting was one of the most useful meetings he had ever attended. It was a forum where all importers from countries outside the EU attended to discuss requirements for meeting EU standards (i.e., not just HACCP requirements but also requirements demonstrating that foods are being produced under EU-mandated standards,

etc.). Sundlof was amazed that what most people would consider the least developed countries in the world have been able to put systems in place to meet those very high European standards. There is a lot to be learned from that: It is possible to meet very high food safety standards when there is market incentive and with sufficient technical capacity or support.

Raymond agreed that any time experts with an interest in food safety meet the meeting is useful, no matter where the meeting is held. He mentioned that in fact the USDA already meets with some of those stakeholders regularly, for example through FAS and Codex (i.e., with respect to the food safety aspects of free trade agreements with Mexico and elsewhere) and as part of an organization known as QUAD (i.e., the Quadrilateral Group). QUAD is a collaborative group comprising food safety experts from Australia, Canada, New Zealand, and the United States. Australia, Canada, and New Zealand account for about 75 to 80 percent of imports into the United States. So there is a lot of this type of interaction and dialogue under way, he said, although nothing on the scale of the Beijing meeting. Raymond commented that he was unsure who would sponsor such a meeting.

Robach suggested that it might be possible to engage the United Nations (e.g., FAO), given its interest and work in food security, nutrition, and public health issues in the developing world. He mentioned that one of the most valuable meetings that he regularly attends is a meeting of Cargill food safety professionals from all 66 countries where Cargill operates. The meeting involves discussing key challenges faced over the past year and how those challenges were addressed, making for a tremendous learning opportunity.

DeWaal agreed that such a meeting would be “hugely beneficial” and noted that the CSPI has been trying to set one up with the NGO community but that the funding is unavailable. She mentioned that there is not much interest in standardizing and generating activity at that level.

### *Sustainability and Other Future Issues*

Brackett asked a question about the issue of sustainability and whether the drive to use less energy, reuse water, etc., is sometimes in direct competition with the drive to achieve good food safety. How are the regulatory agencies going to deal with these competing interests? Sundlof replied that federal regulatory agencies are already dealing with some of these issues. As one example, he pointed to USDA’s “scorched earth policy” which involves eliminating wildlife within a certain area of agricultural land in Salinas Valley, California, and the problems created with respect to the loss of natural habitat for many species. Sundlof noted that sustainability in particular is not a major problem yet. When it does become a major problem, the agencies will deal with it in turn.

Robach commented that Cargill has had plentiful opportunities to deal with this sort of issue, for example in Brazil with respect to soybeans, Indonesia with respect to palm oil and in Ghana and the Ivory Coast with respect to cocoa beans. Robach also commented on the zoonotic origin of many food pathogens and the related issues around that. Cargill works with SSAFE (Safe Supply of Affordable Food Everywhere, Inc.) a public–private partnership dedicated to improving food production and control systems in developing countries while fostering sustainable agriculture and fisheries. Other SSAFE participants include, from the private sector, other large companies, like McDonalds, Nestle, and Pfizer, and from the NGO and public sectors, the Wildlife Conservation Society, the Center for Science in the Public Interest, CARE, the World Organization for Animal Health (OIE), and the Food and Agriculture Organization (FAO). Robach said that managing these issues is an ongoing process that requires both sides of each issue working together.

Raymond noted that there are lessons to be learned from other countries, for example Australia which has been struggling with a severe drought and has been forced to use reconditioned water in its slaughter facilities. In the United States, we use antimicrobial rinses as a way to save water. Chile, on the other hand, uses a tremendously high amount of water per bird in its poultry plants as a way to avoid the use of chlorine, since the EU doesn't allow the import of poultry with chlorine.

Finally, DeWaal reminded the Forum and workshop participants of the transient nature of many of the specific issues addressed. Food scarcity, water use, climate change, and zoonotic issues, for example, are going to become much more important issues in the future. Some of what we may be dealing with today may only be a foreshadowing of what it is to come and we need to be thinking beyond the current problems.

Along this line, Doyle pointed to another future issue: the emergence of opportunistic pathogens that lead to serious illness only in certain populations (e.g., immunocomprised individuals) and which may be very difficult for the food industry to manage. He pointed to colitis-causing *Clostridium difficile* as an example. *C. difficile* often infects hospitalized patients being treated with antibiotics, although researchers are increasingly reporting its occurrence outside of the hospital environment as well—including in animal food products (e.g., it has been detected in braunschweiger and other meats). He asked, are we going to have to resort to making canned ham for all in order to protect the small percentage of people who are vulnerable to infection by *C. difficile* (or any other pathogen)? Ensuring safe food for all is going to become more difficult as these opportunistic pathogens continue to emerge.



# A

## Workshop Agenda

### Managing Food Safety Practices from Farm to Table

The National Academy of Sciences  
Lecture Room  
2100 C Street, NW  
Washington, DC

September 9, 2008

8:00–  
9:00 am      **Registration**

#### INTRODUCTION

9:00 am      **Welcome from Food Forum**  
*Michael Doyle, University of Georgia*

**Objectives of the Meeting**  
*Ned Groth, Groth Consulting Services*

9:10 am      **Keynote Address: Institutional Roles in Risk-Based  
Management**  
*Michael Taylor, George Washington University*

#### SESSION 1: RECENT OUTBREAKS IN VARIOUS FOOD PRODUCTS: LESSONS LEARNED

*Moderator: Henry Chin, Coca-Cola Company*

9:30 am      **Risk Management for Produce**  
*Will Daniels, Earthbound Farms*

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**9:50 am Risk Management for Thermally Processed Foods**  
*Donald Zink, FDA/CFSAN*

**10:10 am Risk Management for Meat**  
*Randall Huffman, AMI*

**10:30 am Consumer Behavior in Managing Food Safety Risks**  
*Christine Bruhn, University of California, Davis*

**10:50 am Q&A with Speakers**

**11:10 am BREAK**

**SESSION 2: STRATEGIC APPROACHES TO OUTBREAK CONTROL**

*Moderator: Janet Beauvais, Health Canada*

**11:30 am Industry Perspective on Managing Risks in a Global Economy**  
*Robert Brackett, Grocery Manufacturer's Association*

**11:50 am Technological Improvements in Outbreak Prevention and Management**  
*Russell Flowers, Silliker Labs*

**12:10 pm Roles and Responsibilities of Industry and Government in Managing Relationships with Global Food Suppliers**  
*Julie Caswell, University of Massachusetts, Amherst*

**12:30 pm Q&A with Speakers**

**1:00 pm Break for Lunch (on your own)**

**SESSION 3: FUTURE SOLUTIONS**

**2:00 pm Panel Discussion: Where Do We Go From Here?**

*Moderator: Michael Doyle, University of Georgia*

*Panelists:*

*Stephen Sundlof, FDA/CFSAN*

*Caroline Smith DeWaal, CSPI*

*Mike Robach, Cargill*

*Richard Raymond, USDA/FSIS*

**3:15 pm Open Discussion**

**4:40 pm Adjourn**





## B

### Workshop Participants

James D. Astwood  
ConAgra Foods  
Omaha, NE

Janet Beauvais  
Health Canada  
Ottawa, Ontario

Geoffrey Becker  
Library of Congress  
Washington, DC

DeAnn Benesh  
3M Co.  
St. Paul, MN

Donna Blum-Kemelor  
USDA  
Alexandria, VA

Rebecca Buckner  
FDA  
College Park, MD

Francis Busta  
University of Minnesota  
Saint Paul

Kristina Butts  
National Cattlemen's Beef  
Association  
Washington, DC

Jean Buzby  
USDA  
Washington, DC

Frederick Caison  
GAO  
Washington, DC

Elizabeth Calvey  
FDA  
College Park, MD

Ricardo Carvajal  
Hyman, Phelps & McNamara, P.C.  
Washington, DC

Julie Caswell  
University of Massachusetts  
Amherst

Britt Erickson  
Chemical & Engineering News  
Washington, DC

Nancy Chapman  
N. Chapman Associates  
Washington, DC

Andrew Estrin  
FDA  
College Park, MD

Alex Chasick  
Consumers Union  
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Vasiliki Flari  
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Yuhuan Chen  
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Steven Gendel  
FDA  
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Kerry Dearfield  
USDA  
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Elise Golan  
USDA  
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Mary Denigan  
GAO  
Washington, DC

David Goldman  
USDA  
Washington, DC

Darinka Djordjevic  
ILSI North America  
Washington, DC

Heather Green  
Association of Public Health  
Laboratories  
Silver Spring, MD

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DoD Veterinary Services Activity  
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Caren Wilcox  
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Katherine Young  
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Jennifer Smith  
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## C

### Speaker, Moderator, and Discussant Biographies

**Janet Beauvais, Ph.D.**, is the Director General of the Food Directorate at Health Canada. The Food Directorate's function is to advise on, and assess the food safety and nutritional issues associated with the food supply. The Food Directorate consists of 400 staff members with expertise in a wide range of scientific and technical disciplines. Areas of work include food additives, chemical and microbiological contaminants, nutritional quality, novel foods and food components, and processes. These responsibilities are carried out through coordinated programs of scientific research, evaluation, and regulatory activities.

**Robert E. Brackett, Ph.D.**, serves as Senior Vice President and Chief Science and Regulatory Officer at the Grocery Manufacturer's Association (GMA). In this role Dr. Brackett oversees all of the association's scientific and regulatory activity, including the operation of its in-house food safety laboratory. He previously served as Director of the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN). Dr. Brackett is an active member of the American Society for Microbiology, the Institute of Food Technologists, and is also a Past-President of the International Association for Food Protection and is the recipient of numerous professional awards in food safety.

**Christine Bruhn, Ph.D.**, is a University of California, Davis (UC Davis) food-science marketing specialist, director of the UC Davis Center for Consumer Research, and a national expert on consumer attitudes about food. She is past chair of the Food Science Communicators, the Nutri-

tion Division, and the Annual Meeting Committee. Dr. Bruhn's research focuses on consumer issues in food safety and quality, including consumer attitudes toward new food production methods or processing technologies. She investigates consumer food handling practices, quantifies food safety concerns, explores consumer information needs, and identifies preferred sources of information.

**Julie A. Caswell, Ph.D.**, is Professor and Chair of the Department of Resource Economics at the University of Massachusetts, Amherst. Her research focuses on understanding the operation of domestic and international food systems, with particular interest in the economics of food quality and labeling, especially for safety and nutrition, and international trade. Dr. Caswell has provided her expertise to the UK Food Standards Agency, the UN Food and Agriculture Organization, and the Organization for Economic Cooperation and Development on food safety issues. She is a member of the Food Marketing Policy Center and Food Safety Research Consortium, and has held numerous senior positions in the Agricultural and Applied Economics Association.

**Henry Chin, Ph.D.**, is the Senior Director of Scientific and Regulatory Affairs at The Coca-Cola Company. Dr. Chin is responsible for product safety, regulatory compliance, and external scientific relations. Prior to joining Coca-Cola, he was with the National Food Processors Association (NFPA) for 28 years. At NFPA, Dr. Chin held positions as Vice President of the Laboratory Centers, with responsibility for analytical chemistry, food microbiology and process development, and as Vice President of Toxicology and Food Science, with responsibility for food safety programs related to food composition, and chemical contaminants.

**Will Daniels** is the Vice President of Quality, Food Safety and Organic Integrity at Earthbound Farm. He has been with Earthbound Farm since 1999, helping the company grow from a small, regional salad producer to the nation's largest grower, packer, and shipper of organic produce. In his current role, Mr. Daniels is responsible for leading the continued enhancements to Earthbound Farm's food safety program, including work on Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), and the Hazard Analysis Critical Control Point (HACCP) program, which includes the implementation of the two-level "Test & Hold" process. Mr. Daniels is an active leader in the organic industry; he also serves on the board of directors of California Certified Organic Farmers as Chair, as well as being President of the Processor/Handler Chapter and serves on the Technical Advisory Committee of the United Fresh Produce Association.

**Caroline Smith DeWaal** directs the food safety program at the Center for Science in the Public Interest. Ms. DeWaal is the leading consumer analyst on reform of laws and regulations governing food safety. Since 1999, she has maintained and annually published a listing of foodborne illness outbreaks organized by food source that now contains over fifteen years of outbreaks reports. She has published numerous journal articles in both science and legal publications and co-authored *Is Our Food Safe?: A Consumer's Guide to Protecting Your Health and the Environment* (Three Rivers Press, 2002). She has participated in a number of World Health Organization consultations on food safety, and is an expert advisor to WHO on the Intergrated Surveillance of Antibiotic Resistance project. She represents the International Association of Consumer Food Organizations at the Codex Committee on Food Hygiene. She has participated in several national advisory committees to USDA and FDA.

**Michael P. Doyle, Ph.D.**, is Regents Professor of Food Microbiology and director of the University of Georgia Center for Food Safety. Previously, he was Distinguished Professor of Food Microbiology and Toxicology at the University of Wisconsin. Dr. Doyle's research program promotes collaboration among the food industry, the university, and federal and state agencies. His research focuses on developing methods to detect and control foodborne bacterial pathogens at all levels of the food continuum, from the farm to the table. He is internationally acknowledged as a leading authority on foodborne pathogens, especially *Escherichia coli* O157:H7. His National Academies service includes chairmanship of the Committee on the Review of the USDA *E. coli* O157:H7 Farm-to-Table Process Risk Assessment and participation in the 2004 *US-Iranian Workshop on Food Safety*, the National Research Council Committee on National Needs for Research in Veterinary Science, and the IOM/NRC Committee to Ensure Safe Food from Production to Consumption. He currently chairs the Food and Nutrition Board's Food Forum. He was elected to the Institute of Medicine in 2003.

**Russell Flowers, Ph.D.**, is a leading researcher, lecturer, and writer on the safety and quality of food products. As Chairman of the Board and Chief Scientific Officer of Silliker Group Corp (SGC), Dr. Flowers' principal responsibilities lie in spearheading strategic growth opportunities, pursuing scientific and technological advances for SGC, and working with professional associations and key customers. A recipient of numerous industry awards and honors, Dr. Flowers is an active member of the several professional organizations and societies including ICMSE, AOAC INTERNATIONAL, Institute of Food Technologists (IFT), and Society



for Industrial Microbiology, International Association for Food Protection (IAFP), and the International Dairy Foods Association (IDFA).

**Edward Groth III, Ph.D.**, is a Consultant with Groth Consulting Services. His main areas of interest are food safety, toxic chemicals, risk assessment, and risk communication. He has participated, as a consumer advocate, in public debates and dialogues with government agencies on myriad health and safety issues.

**Randall Huffman, Ph.D.**, joined the American Meat Institute (AMI) Foundation in January 2000 as Vice President of Scientific Affairs and was promoted to President of the AMI Foundation in April 2008. In this capacity he is responsible for the day-to-day activities of the Foundation, including its research initiatives, industry best practices development and educational programming. The AMI Foundation's food safety research agenda assists AMI members and the industry at large in implementing solutions to food safety and meat quality challenges and serves as the liaison between AMI and various scientific organizations. The AMI Foundation sponsors research and educational programming on the major food safety hazards associated with meat processing. This includes efforts to reduce *E. coli* O157 and *Salmonella* both on the farm and within processing facilities as well as research and education aimed at reducing *Listeria monocytogenes* in ready-to-eat meat products. Among various responsibilities, Dr. Huffman has been a part of both the AMI Foundation-led *Listeria* Intervention and Control Task Force and the Beef Processing Best Practices Task Force that have developed and conducted multiple in-depth training workshops for industry and government.

**Richard Raymond, M.D.**, was appointed as Under Secretary for Food Safety in 2005. In this position Dr. Raymond is responsible for overseeing the policies and programs of the Food Safety and Inspection Service (FSIS), and he chairs the U.S. Codex Steering Committee, which provides guidance to U.S. delegations to the Codex Alimentarius Commission. Dr. Raymond has extensive experience in developing and implementing policies and programs designed to improve public health. Dr. Raymond established and directed a community-based Family Practice Residency for Clarkson Medical Center, served as president of the Nebraska Medical Association, chaired Nebraska Governor Mike Johanns' Blue Ribbon Panel on Infant Mortality and served on numerous state committees related to public health.

**Michael Robach** joined Cargill in January 2004 to lead the company's global food safety and regulatory affairs programs. In this role he leads Cargill's corporate efforts across food safety, regulatory compliance, animal

health, and quality assurance. Mr. Robach began his career with Monsanto Company and prior to joining Cargill, he headed up technical services for Wayne Farms, LLC.

**Stephen Sundlof, D.V.M., Ph.D.**, is Director of the Center for Food Safety and Applied Nutrition, Food and Drug Administration. In this capacity, he provides executive leadership to the Center's development and implementation of programs and policies relative to the composition, quality, safety, and labeling of foods, food and color additives, dietary supplements, and cosmetics. Prior to joining the FDA, he was a professor at the University of Florida, College of Veterinary Medicine. Dr. Sundlof has published numerous articles in scientific journals on drug residues and food safety. He served as chairman of the WHO/FAO Codex Alimentarius Committee on Residues of Veterinary Drugs in Foods from 1994-2008 and is a past president of the American Academy of Veterinary Pharmacology and Therapeutics. He received both his Doctorate in Veterinary Medicine and Ph.D. in toxicology from the University of Illinois, and is a diplomat of the American Board of Veterinary Toxicology.

**Michael R. Taylor, J.D.**, is a research professor in the Department of Health Policy at George Washington University School of Public Health and Health Services. Prior to joining the university, he was a professor in the School of Medicine and a senior research scholar in the School of Public Policy at the University of Maryland. He has extensive experience in the public sector, having served in the FDA as a staff lawyer from 1976 to 1981 and as deputy commissioner for policy from 1991 to 1994, and as administrator of the USDA's Food Safety and Inspection Service from 1994 to 1996. Mr. Taylor is chair of the Steering Committee of the Food Safety Research Consortium, a collaborative effort among research institutions to improve the effectiveness of the food safety system, and conducts research on policies of the that affect agricultural development and poverty reduction in Africa.

**Donald L. Zink, Ph.D.**, is the Acting Senior Science Advisor at the FDA's Center for Food Science and Applied Nutrition. In his current position, Dr. Zink is responsible for providing advice regarding the science policy and strategic direction of the Center and coordinating the Center's research portfolio. During his nearly 30-year career, Dr. Zink has advanced food safety best practices in industry, academia, and government, including Future Beef Operations, LLC; Nestle, USA; Carnation Co; Campbell Soup Co; The University of Arizona; and Texas A&M University. Dr. Zink is a member and subcommittee chairman of the National Advisory Committee on Microbiological Criteria for Foods.



## D

### Acronyms and Abbreviations

AMI	American Meat Institute
AMS	Agricultural Marketing Service
BRC	British Retail Consortium
BSE	bovine spongiform encephalopathy
CAC/Codex	Codex Alimentarius Commission
CDC	Centers for Disease Control and Prevention
CDHS	California Department of Health Services
CFSAN	Center for Food Safety and Applied Nutrition (part of FDA)
CMC	Canadian Meat Council
CSPI	Center for Science in the Public Interest
DAIG	Data Analysis Integration Group (a group at USDA)
DHS	Department of Homeland Security
EHEC	Enterohaemorrhagic <i>E. coli</i>
EU	European Union
EUREPGAP	Euro-Retailer Product Working Group GAP
FACA	Federal Advisory Committee Act
FAO	Food and Agriculture Organization (part of UN)
FAS	Foreign Agricultural Service (part of USDA)
FDA	Food and Drug Administration

FEMA	Federal Emergency Management Agency
FMI	Food Marketing Institute
FSIS	Food Safety and Inspection Service (part of USDA)
FSRC	Food Safety Research Consortium
GAP	Good Agricultural Practices
GAqP	Good Aquaculture Practices
GHP	Good Handling Practices
GMA	Grocery Manufacturers Association
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
IOM	Institute of Medicine
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
NGO	Non-governmental organization
NRC	National Research Council
OIE	World Organization for Animal Health
PACA	Perishable Agricultural Commodities Act
PFGE	pulsed field gel electrophoresis
QUAD	Quadrilateral Group
RFP	Request for Proposal
RTE	ready-to-eat
SPS	Sanitary and Phytosanitary
SQF	Safe Quality Food
SSAFE	Safe Supply for Affordable Food Everywhere, Inc.
S.T.O.P.	Safe Tables Our Priority
UN	United Nations
USDA	U.S. Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organization