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## **Career Focus**

I have worked for more than 30 years on food and agriculture issues, and most recently served as the Prevention Manager for the Food and Drug Administration's (FDA) Coordinated Outbreak Response and Evaluation network (CORE).

I am reestablishing my consulting practice with a focus on the prevention of foodborne illnesses through directly sharing my experience and broad understanding of FSMA requirements relating to human food, produce and animal feed. My consulting practice is built upon many years of experience, and previous roles in the Federal government, trade associations and the private sector.

I am a Food Safety Preventive Controls Alliance (FSPCA) certified Preventive Controls Qualified Individual (PCQI) as well as a Certified Foreign Supplier Verification Qualified Individual (FSVP QI). I also am involved in coordinating a national educational initiative to help produce growers understand the Produce Safety Rule. I have also been through the Produce Safety Alliance Producer Grower Training. These areas of expertise afford me an opportunity to assist select food companies, food industry sectors, and organizations involved in food production, processing, manufacturing and delivery to consumers.

I particularly look forward to sharing my foodborne disease outbreak and prevention-oriented experiences gained while serving for more than four years as the Prevention Manager for the CORE network.

During my time with CORE, I was engaged in efforts to detect, respond, and evaluate prevention opportunities associated with over 100 significant outbreaks. From my vantage point in CORE, I have been able to "see" the inside of entire outbreak scenarios from their earliest detection through resultant company and FDA compliance actions.

My goal is to utilize my knowledge and experience to help companies and farms comply with FSMA regulations, prevent foodborne illness outbreaks, and effectively navigate and manage an outbreak (recall plans, media strategy, etc.) if a food safety system failure has occurred.

This experience builds upon my previous work experience assisting in the development and implementation of the U.S. Department of Agriculture's Food Safety and Inspection Service meat inspection reforms. I played a key role in meat inspection reform discussions, testifying before Congress, and contributing to the notice and comment rule-making process. My involvement helped ensure regulatory reforms and associated regulations were science-based and focused on the hazards analysis and critical control points (HACCP) approach to food safety. These efforts were in direct response to the Jack in the Box *E. coli* O157:H7 outbreak in the early 1990's.

I believe that achieving food safety prevention goals isn't just a cost of doing business, but the prevention analysis process can also result in improvements in the competitiveness and profitability of the food production, processing, manufacturing and retail sectors.

### **Career Summary**

During the past 30 years of my career I have gained an understanding and practical experience working within key entities and organizations that comprise the "fabric" of the food and agriculture sectors. I have sought progressively more responsible employment within the university, government, trade association, and private sectors.

The "fabric" of the food and agriculture sector is a tapestry of hard working professionals. These individuals are farmers and ranchers; within companies that harvest, process, manufacture, distribute, and serve food, industries that provide technology; in the government agencies that serve and regulate the food and agriculture sector, and within colleges and universities that work to increase the sustainability, efficiency, and profitability of food production. Additionally, consumer groups, trade associations, and others are an important part of this "fabric".

I have acquired both an understanding of these entities and direct experience working within or with virtually all facets of the farm to table continuum.

### **Career Related Areas of Experience and Expertise**

- Scientific knowledge and experience-based skills relating to complex and critical food production, food safety issues, and related environmental antecedents/root causes.
- In-depth knowledge and experience supporting my ability to analyze and manage complex food safety issues and challenges, and to develop prevention-oriented solutions.
- Experience supporting an understanding of how to build and maintain coalitions, find the "win-win" scenarios, and develop sustainable, focused, and high performing organizational cultures within industry sectors and food supply chains.
- An ability to effectively develop, and reliably communicate, highly technical and often emotionally charged information to diverse audiences. This includes experience testifying before Congress and serving as an industry spokesperson through all forms of communication media (print, radio, television) including appearances on all national network news broadcasts, and the Oprah Winfrey Show.

## **Current Employment**

### ***President G.M. Weber Consulting, LLC/WeberFoodSafety.Com***

August 2017-Present

Responsibilities: Utilize over 30 years of experience resultant from successfully working across a continuum of high-profile professional positions at the university, U.S. Department of Agriculture, trade association, private sector and the U.S. Food and Drug Administration to provide FSMA/prevention-oriented food safety technical guidance to the production agriculture sector, companies engaged in food production, processing, manufacturing, food service and trade associations representing these sectors. I also provide expert witness and consulting assistance for those considering or engaged in legal action related to food safety and foodborne illness.

### ***Specific Areas of Contemporary Expertise***

A comprehensive understanding of the “inside” processes of detecting, responding, and preventing foodborne illnesses and the many partners that contribute to successfully addressing illness clusters and outbreaks.

A wide range of experiences relating to more than 100 significant foodborne illness outbreaks across many pathogens and food/pathogens pairs, including insights into environmental and production-related antecedents and prevention strategies.

An understanding of how to interpret whole genome sequencing data, and how it is changing outbreak detection and case definitions.

An understanding of how FSMA is intended to alter how food safety hazards are to be addressed, including risk-based preventive controls and how historic domestic and global outbreak data can be effectively utilized to determine hazards. I am a certified PCQI and FSVP QI.

An understanding of how to utilize FDA form 483 and Establishment Inspection Reports (EIRs) to evaluate supply chain risks and prevention opportunities.

As the supervisor for the CORE related Freedom of Information Act (FOIA) requests I have a complete knowledge of the importance of the discovery process, the ability to evaluate if all records are provided, and how to interpret records and associated data.

An understanding of the critical elements important in preventing and responding effectively to outbreaks and associated crisis management to protect the brand equity of companies.

A functional level of knowledge relating to approaches for designing and conducting environmental assessments and their role in identifying antecedents, root cause and prevention strategies.

## **Previous Employment**

### ***Prevention Manager/Interdisciplinary Scientist at FDA Coordinated Outbreak Response and Evaluation Network (CORE)***

May 2013 – July 2017 (4 years 3 months)

Responsibilities: I provided leadership and guidance to the Coordinated Response and Evaluation Network (CORE) and other agencies and organizations as it relates to prompt detection and response to reported illnesses clusters or outbreaks, and post response/prevention efforts associated with FDA-regulated products. The goal of CORE is a safer food supply based upon outbreak-based support for implementation of a science based regulatory framework. Additionally, the goal of CORE is to support collaborative interactions that utilize outbreak related lessons learned to create prevention-oriented interactions with the food production, processing, manufacturing, distribution, and food service sectors.

While with CORE I was engaged in more than 100 significant, high-profile foodborne illness outbreaks. I contributed to the development of prevention-oriented analysis relating to repeated food and/or food pathogen pair outbreaks. I also provided leadership that contributed to the Office of Regulatory Affairs (ORA) finalizing the Environmental Assessment Process document and utilizing it to develop a draft regional environmental procedures document.

I supervised the Freedom of Information Act (FOIA) requests for information that CORE had “custody and control” over. I provided feedback to the FOIA office that they shared with attorneys relative to approaches to best provide them the information they may need.

### ***CORE Related Outbreak Detection, Response and Prevention Experience 2013-2017 Pathogens and Related Food Vehicles***

#### ***E. coli: O121, O26, O157:H7, O111***

Leafy Greens, Flour/dough-based products, Alfalfa Sprouts, Romaine Lettuce, Chicken Salad/celery, Green Cabbage, and Spinach

#### ***Cyclospora cayetanensis***

Bagged Salad, Cilantro

#### ***Hepatitis A and Strain 1b***

Scallops, Pomegranate Arils, Strawberries

#### ***Listeria monocytogenes***

Frozen Vegetables, Soft Cheese, Hummus, Leafy Greens, Stone Fruit, Ice Cream, Caramel Apples

## **Norovirus**

Oysters

## ***Salmonella***

*enteritidis, anadem, braenderup, oranienburg, paratyphi B variant, weltevreden, reading, abony, cubana, bredeney, bovismorbificans, bareilly, agona, javiana, newport, heidelberg, mbandaka, montevideo, stanley, saint paul, senftenberg*

Cucumbers, Hot Peppers, Pistachios, Leafy Greens, Tuna, Shell Eggs, Sprouts, Yellow Onions, Pine Nuts, Sesame Seeds, Pistachios, Mung Bean Sprouts, Papaya, Tomatoes, Peanut Butter, Romaine Lettuce, Cashews

## **Seafood Toxins**

Scrombrotoxin, Tetrodotoxin, Ciguatera, Rhabdomyolysis, Buffalo Fish, Barracuda, Mackerel, Tuna (Ahi, Yellowtail), Mahi Mahi, Escolar

## ***Vibrio parahaemolyticus***

Clams, Oysters

## **Previous Employment. (continued)**

### ***President Food Safety-USA at Bioniche Life Sciences***

April 2008 - April 2012 (4 years)

Responsibilities: Provided leadership to Bioniche Life Sciences in support of efforts to license, commercialize and market a vaccine to reduce the shedding of *E. coli* O157:H7 for cattle in the United States. This included interactions with the produce industry, cattle production, and beef processing sectors, as well as Congress, regulatory agencies, and the media.

### ***President G.M. Weber and Associates, LLC***

June 2007 - April 2013 (5 years 10 months)

Responsibilities: Utilized 26 years of experience working at State and Federal levels leveraging leadership skills and knowledge resultant from highly successful roles at the university, government, trade association, and private sector levels to provide guidance to trade associations, food and agriculture companies, and the government.

Key areas of expertise included working effectively with government regulatory agencies, Congress, the media, farmers and ranchers, and the food industry on matters pertaining to food safety, meat inspection, antibiotic use, animal welfare, the environment, and issues/"crisis" management.

***Executive Director Regulatory Affairs at National Cattlemen's Beef Association***

August 1994 - August 2006 (12 years)

Responsibilities: Developed strategic and tactical plans to address complex regulatory and related legislative issues facing the cattle industry. Provided leadership to develop and manage complex, inter-organizational and inter-governmental coalitions to manage animal health and food safety (meat inspection reform) issues at the State and Federal government level.

Ensured that the development and implementation of Federal legislation and regulations were science-based and consistent with the “grassroots” policies of beef cattle producers. Served as the primary science advisor and media spokesperson for issues such as Mad Cow Disease, meat inspection reform/HACCP, antibiotic resistance, issues associated with zoonotic animal diseases and performance/efficiency technologies, animal care and welfare.

***National Program Leader Animal Science at USDA***

August 1987 - August 1994 (7 years)

Responsibilities: Provided leadership and guidance for the development of approved State Land-Grant University (1862 and 1890) plans of work. Organized, developed, and managed special projects and grants to develop educational programs and materials for the Extension System (ES) through establishing and managing collaboration and development of consortiums with universities, farmers and ranchers, trade association, and animal health professionals.

***Extension Area Livestock Specialist, Adjunct Assistant Professor at Michigan State University***

February 1984 - August 1987 (3 years 7 months)

Responsibilities: Developed and distributed educational materials, organized and conducted educational programs and meetings for beef and swine producers; conducted detailed farm enterprise analysis to aid producers in developing financial and economic cost of production estimates; develop computer decision-support systems for use on beef feedlots and swine farms; conduct beef feedlot nutritional and management troubleshooting.

**Work Related International Travel Experience**

Australia, New Zealand, Great Britain, Uruguay, Mexico, Panama, Syria, and Indonesia

## **Volunteer Experience**

### ***Instructor at Kennard Elementary After School Science and Technology Program:***

*Fall 2017*

"Gross Foodology" for 3 to 5th grade students. Developed a comprehensive, age appropriate program to help students understand food safety and how to prevent illness.

### ***Member at Baltimore-Washington Thurgood Marshall International Airport Neighbors Committee***

2000 - 2006 (6 years)

Appointed to serve on the Baltimore-Washington International Airport Neighbors Committee. This committee is an organization that deals with the impact of the airport on surrounding communities.

### ***President at Elmhurst Improvement Association***

2003 - 2004 (1 year)

The Elmhurst Improvement Association represents the collective interests of over 300 homeowners in the Severn, Maryland area. The association works to protect the homeowners and their families from the impact of development, airport noise, and other threats to their quality of life, and property value.

### ***Vice President at Elmhurst Improvement Association***

2001 - 2002 (1 year)

### ***Member at Baltimore-Washington Thurgood Marshall International Airport Community Enhancement Grant Program***

2001 - 2007 (6 years)

This board reviews and approves community enhancement grants totaling over \$300,000 per year to communities impacted by the airport and associated development. I worked with Maryland State Senator James E. DeGrange to establish legislation to provide for the community enhancement grant program. This included testifying before the Maryland State Senate in support of the program.



## **Publications**

***Insights: Truth as a Commodity. John Dunham and Associates Monthly Manifesto December 25, 2012 Authors: Gary M. Weber, Ph.D.***

As we enter a new year, it is important to contemplate the value of trust as a commodity; how to acquire it, maintain it and the cost of losing it. A select representation of past and present examples of the value of trust and the risk and cost of losing it are discussed.

***Opportunities to Reduce the Risk of Shedding of E. coli O157 by Cattle. USAHA/AAVLD Food and Feed Safety Committee November 14, 2010. Authors: Gary M. Weber, Ph.D.***

Research indicates that vaccination of cattle to reduce the shedding of E. coli O157 has great potential to reduce the levels of the pathogen in and on cattle at harvest and in the environment. This reduction is theorized to significantly reduce the public health risk of E. coli O157 if adoption of the technology is significant. In the short term, vaccination of cattle offers individual branded beef and other companies an opportunity to reduce their risk as well.

***Economic Incentives in Mandatory vs. Voluntary Meat Food Safety Standards: Interagency Risk Assessment Consortium-Economic Research Service November 16, 2007 Authors: Gary M. Weber, Ph.D.***

The beef industry experienced a steady decline in beef demand from the late 1970's through 1996. Consumer confidence played a role in the reduction in beef demand, especially related to concerns regarding nutrition and health.

Food safety became a heightened concern in 1993 (*E. coli* O157:H7) and it became even more a source of concern for consumers with the emergence of Mad Cow disease in 1996. The beef industry from the farm to the table and the Federal government (USDA and FDA) took aggressive actions to reduce these risks.

Foodborne illness especially associated with *E. coli* O157 declined rapidly and prevention steps regarding Mad Cow Disease increased consumer confidence. The demand for beef, defined as more beef sold at higher prices, increased beginning in 1996 and provided continued incentives for the beef industry to invest in prevention. A relatively high level of risk from *E. coli* O157 remains, linked to costly product recalls, loss of brand equity, and large financial settlements related to injury claims. There is more that can be done on the pre-harvest front to reduce risks, yet it is uncertain how the beef industry can monetize the value of these investments. In doing so cattle producers must recognize that virtually every penny packers and processors spend in plants

to reduce risk, every pound of diverted or recalled product and every financial settlement must be amortized into lower bids on live cattle because these costs cannot be transferred efficiently to consumers. These realities, if understood, should help the beef industry decide how to reduce risk in the most cost-effective manner and correspondingly balance the need for more mandatory and prescriptive measures implemented by Federal and State governments.

***Risk Analysis, Action and Communication: BSE Case Study: Would Responding to FMD be Different? USAHA/AAVLD Committee on Animal Emergency Management November 5, 2005. Authors: Gary M. Weber, Ph.D.***

While the public's concerns regarding, Bovine Spongiform Encephalopathy were and remain significant, an outbreak of Foot and Mouth Disease (FMD) has the potential to cause significant impacts on consumer confidence. The economic impact of the disease plus a decline in consumer demand would cause great harm to the business and consumer marketing climate for the beef industry beyond that caused by a case or cases of BSE. Plans must be made accordingly to prevent an outbreak and to respond promptly if one were to occur.

***The U.S. Department of Agriculture's Bovine Spongiform Encephalopathy Expanded Surveillance Program: House Committee on Government Reform and the Committee on Agriculture July 14, 2004. Authors: Gary M. Weber, Ph.D.***

The USDA Animal and Plant Health Inspection Service (APHIS) has carefully designed a statistically valid sampling program, consistent with OIE recommendations, capable of detecting a very low prevalence of Bovine Spongiform Encephalopathy in cattle over 30 months of age. The laboratory testing methods to be used have the sensitivity and specificity to detect the disease well before cattle would show clinical symptoms. The program was designed to identify the overall risk of BSE in the United States over time.

***New Directions in Regulation Seminar Series: "Mad Cow Disease: New Challenges for U.S. Regulation. Harvard University Kennedy School of Government May 4, 2004 Authors: Gary M. Weber, Ph.D.***

This invited paper and seminar focused on the public policy process, science and risk analysis information that culminated in the FDA promulgating regulations in 1996 and 2008 to prevent a disease that was not detected in North America until 2001.

***Global Health BSE Forum: George Washington University Medical Center Department of Global Health February 5, 2004 Authors: Gary M. Weber, Ph.D.***

This presentation and discussion was designed to clarify for the human medical community what the past, present and future Bovine Spongiform Encephalopathy risk profile appears to be relative to the human health risk of new variant CJD. That risk in North America is low and continues to be reduced over time as the feed restrictions are enforced, specified risk materials prohibitions are in place; live animal inspection is rigorous and surveillance and other additional measures are considered.

***Subcommittee on Human Resources and Intergovernmental Relations of the Committee on Government Reform and Oversight May 10, 1996 Authors: Gary M. Weber, Ph.D.***

The Food and Drug Administration plays an integral role in protecting animal and public health. Specifically, in terms of Bovine Spongiform Encephalopathy (BSE), the agency faces a challenge to design, implement, and enforce science and risk analysis-based regulations prohibiting the feeding of materials that could lead to the amplification and spread of BSE. The proposed regulations currently under review are necessary even though BSE has never been identified in North America. However, taking steps beyond those currently under review is not necessary and would correspondingly not meet the test of a cost benefit analysis.

***Consumer Concerns about Modern Technology in Agriculture: Considerations for Undergraduate and Graduate Teaching J. Anim. Sci. 73:2727-2732 1994. Authors: Gary M. Weber, Ph.D., T.J. Hoban, P.A. Kendall and L.S. Bull***

Agricultural technologies have developed at a pace that has exceeded the rate of understanding of society. This naturally creates concerns and opportunities for cultural clashes, understanding the nature of these concerns and methods to address these concerns needs to be part of curriculum development.

***Factors Influencing Technology Transfer Marcel Dekker, Inc., Animal Biotechnology 3#1:155-163 1992 Authors: Gary M. Weber, PhD***

Technology transfer is a complicated process that is impacted by cultural, societal as well as financial and economic constraints. To effectively transfer technology, it is important to understand the forces and factors that enhance or impede technology transfer.

***Meeting the Needs of 21st Century Agriculture. Extension Committee on Organization and Policy High Technology Commercial Agriculture Task Force 1990 Authors: Gary M. Weber, Ph.D., J. Poley.***

As agricultural production systems change in size and scope, their respective needs change for assistance to acquire and efficiently adopt technology. At the same time, the challenges of small and medium size farms and ranches may differ from that of larger operations, yet they all must meet societal expectations for producing safe, affordable food produced in environmentally sound and socially acceptable ways. Thus, the Land-Grant University, U.S. Department of Agriculture, and County partnerships that are the foundation of the Extension Service network must adapt to these varying needs and expectations. This report outlines a consensus framework for the future.

### **Honors and Awards**

#### **September 2016 Food and Drug Administration Center for Food Safety and Applied Nutrition Leveraging/Collaboration Award**

As a member of the Delmarva Produce Safety Task Force: "For exhibiting exceptional relationship building and instituting a novel regional approach to collaboration and research addressing produce safety from the Delmarva region."

#### **August 2016 Food and Drug Administration Leveraging Collaboration Award**

As a member of the Cyclospora and Cilantro Response Group: "For outstanding performance of investigational and collaboration in response to multi-year outbreaks of cyclosporiasis linked to fresh cilantro from Puebla, Mexico."

#### **August 2016 Food and Drug Administration Group Recognition Award**

As a member of the *Listeria monocytogenes* and Ice Cream Incident Response Group: "For exemplary performance of duties and collaboration in response to a multi-state outbreak of *Listeria monocytogenes* linked to ice cream".

#### **August 2016 Food and Drug Administration Group Recognition Award**

As a member of the *Listeria monocytogenes* and Caramel Apples Incident Response Group: "For exemplary performance of duties and collaboration in response to a multi-state outbreak of *Listeria monocytogenes* linked to caramel apples."

**2015 Food and Drug Administration Group Recognition Award**

As a member of the *Rhizopus oryzae* Incident Response Group: “For outstanding response, collaboration, and communication resulting in the recall of an adulterated product to fill the FDA’s mission, and promote and protect public health.”

**2014 The Food and Drug Administration Office of Foods and Veterinary Medicine Coordinated Outbreak Response and Evaluation and Partners Award**

As a member of the Coordinated Outbreak and Evaluation Network this award is for playing a role in: "The forging of trailblazing relationships between FDA, State, Department of Defense (DOD) and three organizations that respond to foodborne outbreaks, thus protecting public health.

**2012 Purdue University College of Agriculture Distinguished Alumni Award**

**2006 Food and Drug Administration Commissioner’s Special Citation**

“For leadership to Gain Support for Bovine Spongiform Encephalopathy Prevention Regulations”

**2004 Purdue University Department of Animal Science Distinguished Alumni Award**

**1995 American Registry of Professional Animal Scientists: Charter Diplomate of the American College of Animal Nutrition**

**1994 ES-USDA Administrator’s Certificates of Appreciation (2)**

**1992 Epsilon Sigma Phi, Mu Chapter, Team Award**

**1992 USDA Certificate of Appreciation**

**1991 ES-USDA Administrator's Certificate of Merit**

**1989 ES-USDA Administrator's Certificate of Merit**

"For Outstanding Leadership in Coordinating Extension's Role in National Referenda for the Beef and Swine Industries"

**1988 USDA Secretary of Agriculture Citations (2)**

**1987 Michigan Association of County Agricultural Agents President's Award**

**1986 Epsilon Sigma Phi, Michigan Chapter, Team Programming Award**

**1977 Distinguished Graduate, Scholastic Achievement, Purdue University**

## **Education**

### ***Food Safety Preventive Controls Alliance***

Food Safety Preventive Controls Alliance: FSMA Preventive Controls and Foreign Supplier Verification Program Qualified Individual Certifications 2017

### ***Michigan State University (Doctor of Philosophy)***

Animal Science/Husbandry and Production, 1979 – 1984

### ***Purdue University (Master of Science):***

Animal Science, 1977 – 1979

### ***Purdue University (Bachelor of Science)***

Animal Science, Distinguished Graduate, 1973 – 1977

Purdue University Department of Animal Science Distinguished Alumni Award 2004

Purdue University College of Agriculture Distinguished Alumni Award 2012