



# Journal of the Association of Food and Drug Officials

*Serving the regulatory community since January 1937*

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## From the Executive Director

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### **Food Safety Summit – Town Hall Meeting**

**Joe Corby, Executive Director**

**Association of Food and Drug Officials**

**2013 Food Safety Summit**

**Baltimore, MD – May 2, 2013**

*(transcribed)*

My sincere thanks to the Food Safety Summit for allowing me the privilege to share a stage with Mike Taylor; FDA and Dr. Elizabeth Hagan; USDA/FSIS. It is also a privilege, as always, to represent state and local food protection officials who I believe will play a key role in a food safety system that has been prescribed under the Food Safety Modernization Act (FSMA).

During the Summit this week I heard a number of speakers state that today is an important, critical, and challenging time for food safety. When I spoke on the FSMA panel, I compared the events of today with the events that occurred in 1906 and 1938. Both of these years were pivotal for FDA because they included the adoption of new and sweeping food and drug law. I said during the panel that I thought what is occurring with FSMA today is bigger and more instrumental to food protection than what happened way back then.

Today, I am asked what I believe is our most pressing food safety issue. Few of you will be surprised to learn that I believe our most pressing calling is for integrating our food safety system. In my opinion it is the only way we can dramatically improve food safety. And unlike 16 years ago when we first began the discussion of integration, we now have FSMA that mandates us to do so. I suggest, therefore, that the debate is now over, and we must continue on a pathway of changing cultures and knocking down those barriers which have prohibited us from integrating in the past. Changing government cultures is not easy and removing these barriers will take time. However, it is very encouraging to note there is currently a great deal happening to advance an integrated food safety system.

I am extremely proud of state and local agencies commitment to this effort. 41 states have enrolled in the Manufactured Food Regulatory Program Standards and some 553 state and local jurisdictions are enrolled in the Retail Food Regulatory Program Standards. In addition, 19 states are active in the development of Rapid Response Teams. Stakeholder alliances consisting of government, industry, academia, and consumer officials for produce safety, food safety preventive controls, sprouts, and seafood are developing the necessary education and training that is needed. The Partnership for Food Protection [PFP], which has been in existence for several years, is helping in directing our efforts in enhancing an integrated system. These are all strong and positive signs.

Our outbreak and surveillance systems will all be enhanced through the work of OutbreakNET, NoroCORE, the Council to Improve Foodborne Outbreak Response [CIFOR], and the Rapid Response Teams previously mentioned. There is a coordinated effort to strengthen our public health and food and feed testing laboratories by building a lab accreditation system that will allow us to better share the important work conducted here.

All of these efforts and many more that exist are looked at very favorably by state and local officials, and they serve testimony to those food protection pioneers who 16 years ago first offered the vision of an integrated food safety system up.

What does all of this tell me? It tells me that something great is about to happen in the world of food safety. Many people ask me when this integration effort will begin as if there was a specific date set for the country. I think a better question is how will you know integration has begun?

If you are with industry, I think you will begin to notice more uniform and consistent inspections particularly if you have plants located in multiple FDA Districts or multiple states. I also believe you will see that government agencies respond more effectively and in a more coordinated fashion when illnesses or episodes occur.

If you are with academia you will know this effort has begun because we will have sought your wisdom, science, and guidance in training the multitude of industry and government officials in the coming years. You will help us with industry, and particularly small businesses develop food safety plans designed to prevent illnesses from occurring. And government agencies will finally demonstrate their respect for one another by sharing inspection results, sample results, and data to allow us to operate more effectively and strategically.

Consumers will know because they will finally be able to express confidence in a food safety system which they have demanded and they have deserved.

16 years ago I worked on building an integrated food safety system with Joe Leavitt who was the Director of FDA/CFSAN. Today he is a food law attorney in Washington DC and I spoke with him recently about the renewed integration efforts. He told me that only bad ideas go away and that good ideas always reappear. Integrating the food safety system was a good idea 16 years ago and it is a greater idea today. I look forward to working with every one of you in this mission to build a nationally integrated food safety system.

Thank you so much for the opportunity to share these thoughts with you.

## 2013-2014 AFDO Board of Directors

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<i>President*</i> ∇	David Read
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<i>Secretary/Treasurer*</i> ∇	Steve Moris
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<i>CASA Regional Affiliate Director</i> ∇	Erik Bungo
<i>MCAFDO Regional Affiliate Director</i> ∇	Ashley Nale
<i>NCAFDO Regional Affiliate Director</i> ∇	Katherine Simon
<i>NEFDOA Regional Affiliate Director*</i> ∇	Darby Greco
<i>WAFDO Regional Affiliate Director</i> ∇	Susan Parachini

\* Member of Executive Committee

∇ Voting Board Member

## 2013-2014 AFDO Board-Appointed Advisors

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Dennis Baker, U.S. Food & Drug Administration

Cynthia Culmo, Abbott Laboratories

Sarah Geisert, General Mills, Inc.

Jerry Wojtala, International Food Protection Training Institute

## 2013-2014 AFDO Committee Chairpersons

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### Administration Committee

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### Foodborne Outbreak & Emergency Response Committee

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### International & Gov't. Relations Committee

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### Laws & Regulations Committee

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### Seafood Committee

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**\*Chair is responsible for submission of reports**

# AFDO Regional Affiliates

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## **Association of Food and Drug Officials of the Southern States**

**AFDOSS President..... Mark Reed**  
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## **Central Atlantic States Association**

**CASA President.....Melissa Vaccaro**  
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## **Mid-Continental Association of Food and Drug Officials**

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## **North Central Association of Food and Drug Officials**

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## **North East Food and Drug Officials Association**

**NEFDOA President.....Joyce Welch**  
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## **Western Association of Food and Drug Officials**

**WAFDO President.....Lorinda Lhotka**  
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## 2013 AFDO Award Recipients

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The **Elliot O. Grosvenor Food Safety Award** was presented to the **New York State Department of Agriculture and Markets** for their Bio-Terrorism Imported Food Surveillance Program. Ms. Angela Montalbano, Inspector, accepted the award on behalf of her agency. This award, established in 2010, is given to recognize outstanding achievements made by food safety programs.

The **Harvey W. Wiley Award** is AFDO's most prestigious award. This year's recipient, **Dan S. Smyly, Ph.D.**, was honored for his outstanding service and devotion to the administration of food, drug and consumer protection laws of our country. Dr. Smyly served as the Director of the Division of Food Safety at the Florida Department of Agriculture and Consumer Services prior to joining The Coca-Cola Company as Scientific & Regulatory Affairs Director. Dan retired on March 31, 2013.

The **Associate Member Award** was presented to **Ballard H. Graham**, Divisional Vice President of Compliance Oversight for Abbott Laboratories in Abbott Park, Illinois. The AFDO Associate Award is awarded annually to an associate member based on long term active membership in the Association, active involvement in committee work, development of model codes, and promoting the objectives of AFDO. Ballard retired from his position in 2013.

The 2013 **Achievement Award** was presented to **Valerie Gamble, MS, REHS**, Agricultural Advisor with the Minnesota Department of Agriculture in St Paul, MN. The Achievement Award is annually bestowed on an individual who has demonstrated exemplary performance within their field in their first five years of service.

AFDO awards three scholarships annually in the amount of \$1,500 each. The "**George M. Burditt Scholarship**", "**Betsy B. Woodward Scholarship**" and the "**Denise C. Rooney Scholarship**" are each awarded to an undergraduate student in their third year of college who has demonstrated a desire to service in a career of research, regulatory work, quality control, or teaching in an area related to some aspect of foods, drugs or consumer product safety. This year's recipients were:

**Angela Davis**, Alabama A&M University, Huntsville, AL  
**Jessica Louie**, Rutgers University, New Brunswick, NJ  
**Breanna McArthur**, Alabama A&M University, Huntsville, AL



## 2013 AFDO Resolutions

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### *RESOLUTION NUMBER 2013-01*

**Submitted by:** AFDO Board of Directors

**Date:** April 4, 2013

**Concerning:** Safety of Food in Relief Systems

**Whereas,** food insecurity is a major, growing concern with an estimated 50.1 million people in the United States who do not have access to enough food and/or nutrition, including 16.7 million children, and

**Whereas,** a staggering amount of food in various conditions from sources throughout the supply chain finds its way to food banks every day where food safety is judged by volunteers before being distributed to relief organizations and individual consumers, and

**Whereas,** food banks may be challenged to provide adequate food safety training to volunteers, especially those that repackage bulk food products or handle other exposed foods, and

**Whereas,** many states have inconsistent or inadequate regulation and inspection of food handled in the relief systems, therefore, be it

**Resolved,** that AFDO provide the National Conference of State Legislators (NCSL) information about the importance of adequate and consistent regulation to protect food in relief channels, and be it further

**Resolved,** that AFDO and IFPTI contact Feeding America and offer assistance in advising on the development of new and comprehensive food safety training programs for food handling volunteers.

## **RESOLUTION NUMBER 2013-02**

**Submitted by:** CASA and amended by AFDO

**Date:** April 4, 2013

**Concerning:** Areca Nut (Betel Nut)

**Whereas,** areca nut (betel nut) is an adulterated food used in paan (betel quid), an ancient food combination of areca nut and slaked lime, wrapped in a betel leaf with optional condiments, and

**Whereas,** areca nut (betel nut) is the fourth most common addictive substance in the world; and

**Whereas,** 10 - 20 percent of the world's population in South East Asia, the Subcontinent of India, and U.S. immigrants and refugees (about 600 million people) practice betel nut chewing culture, and

**Whereas,** betel nut chewing culture has been documented in the United States, and

**Whereas,** areca nut itself has been classified as a Group 1 carcinogen (carcinogenic to humans) by the WHO International Agency for Research on Cancer (IARC, 2004), and

**Whereas,** areca nut is the definitive cause of oral sub mucous fibrosis (OSF), a precancerous condition of the upper digestive tract including the oral cavity, and

**Whereas,** the immigrant and refugee populations that practice betel nut chewing culture are increasing at a greater rate than the general population, and

**Whereas,** areca nut is also a non food religious ritual item.

**Resolved,** that CASA forward this Resolution to AFDO for their consideration and endorsement, and then have it forwarded to FDA, and be it further

**Resolved,** that AFDO advise FDA of this matter and ask them to clarify to State food safety regulatory agencies of its position on areca nut (betel nut) as an adulterated food, any labeling requirements which could exempt it as a food (religious exemption), and what enforcement actions would be appropriate.

## ***RESOLUTION NUMBER 2013-03***

**Submitted by:** AFDO Executive Board

**Date:** April 4, 2013

**Concerning:** Uneviscerated Processed Fish

**Whereas,** uneviscerated processed fish that is salt cured, dried, or smoked can be dangerous, and is addressed by FDA Compliance Policy Guide 540.650 which declares it to be an adulterated food due to the potential for botulism toxin development in the viscera of the fish, and

**Whereas,** clandestine sale of uneviscerated processed fish is difficult for regulatory agencies to fully address with traditional inspection resources because of challenges associated with determining the product source, and

**Whereas,** community perception of regulatory action against uneviscerated processed fish is oftentimes unfavorable, and

**Whereas,** regulatory actions alone cannot address the issue and prevent future demand for uneviscerated processed fish, and

**Whereas,** community engagement has the potential to encourage self-regulation in immigrant communities and allow for education of both regulators and business owners, and

**Whereas,** conventional inspection and enforcement practices with ethnic food business owner operators selling illegal uneviscerated processed fish may not be an optimally effective approach for addressing this matter, therefore, be it

**Resolved,** that AFDO ask FDA to work with them to identify strategies for developing greater collaboration and communication between states (domestic inspections) and FDA (import operations) that could more efficiently remove illegal uneviscerated processed fish from the market, and be it further

**Resolved,** that AFDO request FDA to work with their state partners in local and national community engagement through joint development of educational programs, fact sheets, and training and outreach activities within existing community organizations.

## **RESOLUTION NUMBER 2013-04**

**Submitted by:** AFDO Board of Directors

**Date:** April 4, 2013

**Concerning:** IFPTI Advisory Council

**Whereas,** AFDO recognizes the critical importance of training for industry and regulatory officials that will be required to meet the mandates of the Food Safety Modernization Act (FSMA) and to advance an integrated food safety system, and

**Whereas,** AFDO believes the establishment of an organizational body that can identify specific training needs, coordinate training development and delivery efforts, and advise federal agencies of other related training issues would be a positive advancement for meeting these training challenges, and

**Whereas,** the International Food Protection Training Institute (IFPTI) Advisory Council is already in existence and represents a diverse group of food protection communities including federal regulatory agencies, state and local food protection agencies and associations, industry, consumer advocates, and academia, and

**Whereas,** the participating organizations of the IFPTI Advisory Council include:

Association of American Feed Control Officials, Inc. (AAFCO)

Association of Food & Drug Officials (AFDO)

Association of Public Health Laboratories (APHL)

Association of State and Territorial Health Officials (ASTHO)

Center for Disease Control (CDC)

Cornell University

Council of State and Territorial Epidemiologists (CSTE)

The Food Allergy & Anaphylaxis Network

Food Marketing Institute (FMI)

Global Food Protection Institute (GFPI)

Grocery Manufacturers Association (GMA)

Institute of Food Technologists (IFT)

Iowa State University (ISU)

Michigan State University (MSU)

National Association of County & City Health Officials (NACCHO)

National Association of Local Boards of Health (NALBOH)

National Association of State Departments of Agriculture (NASDA)

National Association of State Meat and Food Inspection Directors (NASMFID)

National Center for Biomedical Research & Training at Louisiana State University (NCBRT)

National Environmental Health Association (NEHA)

Partnership for Food Protection [PFP] Training Workgroup

U.S. Animal Health Association (USAHA)

U. S. Food & Drug Administration [FDA]

USDA Food Safety and Inspection Service (FSIS)

United Fresh Produce Association

, and

**Whereas,** IFPTI is dedicated to improving food safety by providing career-spanning, standards-based training for food protection professionals under a Cooperative Agreement with FDA, and

**Whereas,** the IFPTI Advisory Council is a representative body that has a stake in the training and certification infrastructure for the national integrated food safety system, therefore, be it

**Resolved,** that AFDO request FDA to provide the support and recognition to the IFPTI Advisory Council as the organizational entity that will work with the Partnership for Food Protection [PFP] to assist in the advancement of training and certification identification, development, and delivery necessary to meet the mandates of the Food Safety Modernization Act (FSMA) and to advance an integrated food safety system, and be it further

**Resolved,** that AFDO request FDA to work within the IFPTI Advisory Council for guidance on how training should be prioritized and administered.

## ***RESOLUTION NUMBER 2013-05***

**Submitted by:** AFDO Board of Directors

**Date:** June 7, 2013

**Concerning:** Fellowship in Food Protection

**Whereas,** the Fellowship in Food Protection program, established by the International Food Protection Training Institute (IFPTI) almost four years ago to train federal, state, local, tribal, and territorial food protection personnel, has achieved unprecedented success in meeting training and development objectives; and,

**Whereas,** the Fellowship program has achieved accreditation from the American National Standards Institute (ANSI) thereby assuring continuous high quality that is integral to implementation of the training and leadership requirements for establishing the National Integrated Food Safety System (IFSS); and,

**Whereas,** individuals trained under the Fellowship are the future leaders of food safety in the U.S., with graduates from the Fellowship already achieving leadership positions in their agencies and in national and regional food safety organizations; and,

**Whereas,** the Fellowship program has created networks of journey-level and supervisory leaders through its three cohorts to-date; and,

**Whereas,** it is imperative that the next generation of food safety professionals continue to receive the kind of training in food safety policy and leadership skills that has been provided by the IFPTI Fellowship; and,

**Whereas,** the Association of Food and Drug Officials (AFDO) continues to support the Fellowship both financially and by promoting its concept at every opportunity; be it therefore,

**Resolved,** that AFDO request FDA to officially recognize the Fellowship in Food Protection program as an integral component of achieving a fully Integrated Food Safety System; and, be it

**Further Resolved,** that AFDO request FDA to support the Fellowship in Food Protection program through participation and course recognition in ORA-U and within the integrated national training network.

## **RESOLUTION NUMBER 2013-06**

**Submitted by:** AFDO Seafood Committee

**Date:** June 10, 2013

**Concerning:** Formal request for the release and sharing of the quantitative risk and benefits assessment conducted by the Food and Drug Administration (FDA) that has been published in draft form for public comment since 2009 and is paramount to resolving the inconsistency in fish consumption advice to pregnant women and other at risk populations in the United States

**Whereas,** AFDO approved and issued three Resolutions in May 2011 (copies attached) calling for release of the related information available through FDA, and

**Whereas,** FDA's Deputy Commissioner for Foods, Michael R. Taylor acknowledged the 2011 AFDO Resolutions 1, 2 and 3 through a letter to the AFDO 2012 President, Oscar Garrison (copy attached) indicating their intentions to have the final draft of the assessment due in 2012, and

**Whereas,** the AFDO Seafood Committee and related expertise have continued to discuss and anticipate release of the requested information since 2011, and

**Whereas,** additional science-based information culminating since 2009 provides further evidence in support of resolutions to address inconsistencies in public health advisors regarding exposure to methylmercury, and

**Whereas,** the prevailing public advisors regarding seafood consumption for pregnant women and other at risk populations remain inconsistent between the pertinent federal agencies and public outreach programs, and

**Whereas,** the inconsistencies place a burden on state public health agencies on how to interpret advice on a priority basis, in light of the prevailing science and Dietary Guidelines for Americans; therefore, be it

**Resolved,** that AFDO submits a formal request to release the final version of FDA's "Draft Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population," that has been available only in draft form since January 2009.

## About the Authors

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**Ward Chickoski**, was appointed Regional Director General, Prairie Region in April 2012, after serving as the Associate Regional Director General of Alberta Region, Regions and Programs Branch of Health Canada.

Prior to this Ward was the Deputy Director General, Aboriginal Justice with the Department of Justice in Ottawa and has held senior management, program, policy and operational positions with the Privy Council Office, the Canadian Food Inspection Agency and the Canada Border Services Agency. He served as Director of Public Affairs at the Canadian Food Inspection Agency during the second incidence of bovine spongiform encephalopathy (BSE) in Canada as well as the Avian Influenza outbreak in British Columbia's Fraser Valley.

Ward is pleased to have this opportunity to update you on Health Canada's contributions in relation to food, drug and medical device safety systems.

**Claudia Coles**, is the Administrator of the Office of Compliance and Outreach within the Food Safety and Consumer Services Division of the Washington State Department of Agriculture (WSDA). Previous WSDA positions Claudia has held include the Food Safety Program Manager, Assistant Compliance Program Manager, Regional Food Safety Supervisor, Food Safety Officer and Microbiologist.

The WSDA Food Safety and Consumer Services Division is also home of the Food Safety, Microbiology Laboratory, Organic Food and Dairy Nutrient Management Programs.

Claudia is a member of numerous National Food Safety Committees such as the Association of Food and Drug Officials where she currently holds the President-elect position, the National Conference of Interstate Milk shippers and has holds a variety of board positions on Regional and National Food Safety Associations. Claudia is also a Past President of Western Association of Food and Drug Officials (WAFDO) and the National Association of Dairy Regulatory Officials (NADRO).

Claudia has received five awards from the Commissioner of the US Food and Drug Administration for her consistent leadership in food safety, Seafood HACCP, Interstate Milk Shippers Conference committees such as Dairy HACCP and the International Certification Pilot Program, training teams, and promoting state and federal partnerships.

Claudia earned her Bachelor of Science in Food Science from North Dakota State University and she is a Class 14 graduate of the Washington Agriculture and Forestry Leadership Program.

**Cameron Prince**, has worked for over 35 years in the field of food safety and inspection with the Government of Canada. Beginning his career as a front-line inspector, his career has taken him through various supervisory, management and executive positions across Canada. He has held such positions as CFIA, Vice President of Operations,



Executive Director, Atlantic Operations and Executive Director, Animal Products Directorate.

As of July 4, 2011, Cameron has taken on the important task of moving the CFIA's Modernized Inspection System initiative ahead as Vice President, Inspection Modernization.

Cameron holds an Honours Bachelor of Science Degree from the University of Western Ontario.

**Joseph W. Reardon**, recently joined North Carolina Department of Agriculture & Consumer Services to serve as the Assistant Commissioner for Consumer Protection. In this role, he will oversee the divisions responsible for food safety, agricultural emergency response, animal health and regulation of the structural pest control industry, pesticide use and various weighing and measuring devices.

Mr. Reardon brings a wealth of knowledge and experience in food and feed safety and defense at both the State and federal level. He served as Senior Advisor for Federal-State Relations and Director for the Division of Federal-State Relations in the Office of Regulatory Affairs of the United States Food and Drug Administration (FDA) from 2009 through 2012. In these roles, he worked collaboratively with Federal, State, local, tribal, and territorial partners to enhance the public health infrastructure and served as the point of contact for State programs on matters dealing with food and feed safety and defense.

As the Senior Advisor, he provided the leadership, vision and strategic direction to increase collaboration and communication with Federal, State and local partners to achieve a national integrated food safety system. He co-chaired the Integration Task Force and the Food Safety Modernization Act (FSMA) Federal-State Integration Team in addition to working closely with the Partnership for Food Protection Executive and Coordinating Committees. He served as the FDA representative for several national public health and regulatory professional associations and was the primary contact for State and local regulatory agencies on issues related to Federal-State integration.

Prior to joining the FDA, Mr. Reardon served the North Carolina Department of Agriculture & Consumer Services for more than 28 years in various regulatory positions, including as the Director of the Department's Food and Drug Protection Division and Special Assistant to the Commissioner of Agriculture for Food and Agriculture Projects. He received the Department's coveted Cornerstone Award in 2002-2003 in recognition for his outstanding leadership and commitment in the integral role as coordinator of special agricultural projects.

He has provided testimony before the House Committee on Homeland Security Subcommittee on Intelligence, Information Sharing, and Terrorism Risk Assessment for the State of the Nation report on food defense, animal disease, and potential economic impact of bioterrorism. In addition, he is the co-author of several national articles including Histamine Poisoning in Tuna Burgers and Outbreak of Listeriosis among Mexican Immigrants as a result of Consumption of Illicitly Produced Mexican-Style Cheese.

Mr. Reardon holds a degree in Food Science from North Carolina State University and is currently completing an interdisciplinary program for a Bachelors of Science degree in Emergency Preparedness and Response with the Emergency and Disaster Management Program at Western Carolina University.

**Michael R. Taylor**, was named Deputy Commissioner for Foods at the U.S. Food and Drug Administration, on Jan. 13, 2010. He is the first individual to hold the position, which was created along with a new Office of Foods in August 2009 to elevate the leadership and management FDA's Foods Program. Mr. Taylor is a nationally recognized food safety expert, having served in high-level positions at FDA and USDA, as a research professor in academia, and on several National Academy of Sciences expert committees.

As Deputy Commissioner for Foods, Taylor provides leadership and direction to all food programs in the Agency, including those managed by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM), and the foods-related programs of FDA's inspection and compliance arm, the Office of Regulatory Affairs (ORA).

Mr. Taylor returned to FDA in July 2009 as Senior Advisor to the Commissioner. Before that, he served as Research Professor, School of Public Health and Health Services, The George Washington University. His research agenda focused on policy, resource and institutional issues that affect the success of public health agencies in carrying out their prevention-related missions. Mr. Taylor received his law degree from the University of Virginia and his B.A. degree in political science from Davidson College.

**President's Address**  
**Claudia Coles**  
**Administrator, Office of Compliance and Outreach**  
**WSDA Food Safety & Consumer Services Division**  
**AFDO 117<sup>th</sup> Annual Educational Conference**  
**Louisville, KY -- June 9, 2013**

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Integration is a state of mind:

I want to "Thank" everyone for attending the 117<sup>th</sup> AFDO Educational Conference here in Louisville, Kentucky. Our conference theme this year is: "Implementing the Integrated Food, Drug and Medical Device Safety System". A big "Thank you goes out to the Association of Food and Drug Officials of Southern States or AFDOSS – as well as the industry contributors to this year's gathering.

The Association of Food and Drug Officials (AFDO) was established in 1896 and AFDO's Vision Statement is: *Promoting Public Health, Fostering Uniformity, and Establishing Partnerships*". AFDO's mission is to successfully foster uniformity in the adoption and enforcement of science-based food, drug, medical devices, cosmetics and product safety laws, rules, and regulations.

AFDO and its six regional affiliates: AFDOSS – Association of Food and Drug Officials of Southern States, CASA – Central Atlantic States Association of Food and Drug Officials, MCAFDO – Mid-Continental Association of Food and Drug Officials, NCAFDO – North Central Association of Food and Drug Officials, NEFDOA – North East Food and Drug Officials Association, and WAFDO – Western Association of Food and Drug Officials provide the mechanism and the forum where regional, national and international issues are deliberated and resolved to uniformly provide the best public health and consumer protection in the most expeditious and cost effective manner.

My very first AFDO conference was in 1998 at the 102nd annual conference held in Williamsburg, Virginia. I attended "The World of Food and the Laws that Regulate Them" workshop and the following seminar on Foodborne Outbreak Investigations and Tracebacks: Coordination and Communication in Cooperation with FDA, USDA, CDC.

President Clinton's Food Safety Initiative, Consumer right to know labeling issues on Country of origin (COOL) and genetically engineered foods, BSE prevention measures and FDA/State Contracts, and National Uniformity were just some of the highlighted topics in Williamsburg.

The 1998 AFDO conference was led by then President, Dr. Dan Smyly with the Florida Department of Agriculture and Joe Corby with the New York Department of Agriculture and Markets as President elect. I never thought in 1998 that I would end up in the historical list of AFDO's long line of Presidents. There are so many dedicated people who have helped to make this year and today happen.

Attending the Burditt luncheons over the years helped me to understand and learn more about the history of food and drug laws. I learned that state food, dairy and drug officials travelled for days across the country to meet and influence each other on issues

such as adulterated foods, misbranded food and drugs to lack of uniformity between states. Last year George Burditt provided the history of the 1912 conference that took place in Seattle, Washington, 100 years earlier. This is significant to Washington State as my own agency; the Washington State Department of Agriculture is just now celebrating our centennial year after being established in 1913.

The Burditt Luncheons told the stories of how Harvey Washington Wiley also helped to shape early food and drug regulations, from the "Poison Squads" to how Wiley unified a variety of groups behind a federal law to prohibit the adulteration and misbranding of food and drugs, including state chemists and food and drug inspectors, the General Federation of Women's Clubs, and national associations of physicians and pharmacists. In June 1906, President Roosevelt signed the Food and Drugs Act, which was known simply as the Wiley Act.

In understanding the history of how the Wiley Act came to be, I was surprised to learn the impact of the General Federation of Women's Clubs on such ground breaking legislation. For you see, my Mother was a GFWC member for over 50 years in North Dakota. I grew up in a household where both parents volunteered in organizations including our local church, 4H clubs, potato, sugar beet and grain elevator boards to the General Federation of Women's Clubs. They traveled across the state and country attending meetings and participating in making changes (and life long friends) through these organizations. Their State of Mind was to be active and not sit on the sidelines as change occurs every day.

In 1998 – AFDO called for the creation of a nationally integrated food safety system. This Integration vision has long involved both the regulatory and the regulated community. Federal, State, local and industry groups have been working together through numerous activities such as the Partnership for Food Protection, 50 – State meetings, public meetings on proposed regulations, Alliance working groups and face to face meetings such as AFDO's annual educational conference and committee meetings.

The signing of the 2011, Food Safety Modernization Act (FSMA), is the most significant change to the U.S. food protection system since President Roosevelt signed the 1906 Food and Drug Act (Wiley Act). FDA is mandate to build an integrated food safety system under the Food Safety Modernization ACT (FSMA). Prevention, Intervention and Response are key directives under FSMA.

On Saturday, June 8<sup>th</sup>, 2013, AFDO and the International Food Protection Training Institute (IFPTI) held a pre-conference workshop where participants learned how to use the Integrated Food Safety System Toolkit. Opportunities to learn how to use this toolkit and several other initiatives are helping to move us to an integrated food safety system.

Integration is a state of mind.

We need to continue working together and collaborate on issues if we are going to achieve the vision of integration. When AFDO's Executive director, Joe Corby aka "the AFDO Godfather" discussed integration implementation during the toolkit workshop, he

stated: “Talk the Talk and Walk the Walk”. Barbara Cassens, with the Food and Drug Administration (FDA) used the phrase: “TNT” – “Turf and Trust”

We need to be actively involved in collaborating on issues, trying out new concepts and letting go of turf and other barriers to build the trust that is necessary to achieve the vision of integration. Barbara Cassens also stated at the Toolkit workshop: “Think Globally – Act Locally”

My state of mind is that with active participation in AFDO and our six regional AFDO affiliates across the U.S. and Canada, we have opportunities to work together on common issues for another 117 years. Integration is achievable if we all have a state of mind that we can work together.

I suspect that our forefathers who gathered at those past AFDO meetings did not expect to have many of the same food and drug issues being relevant over a100 years later. Adulteration issues, mislabeling, economic fraud and severe public health impacts still take place since AFDO was originally formed in 1896.

As AFDO’s President, I am honored that I have had the opportunity to attend all six regional affiliate conferences. I have been to Gatlinburg, TN, Pleasanton, CA, Bloomington, MN, Springdale AK, Niagara Falls, NY and Hampton Beach, NH this past year. All of the regional affiliates had outstanding topics that were presented and discussed and had broad participation from industry, local, state and federal members. Through AFDO and WAFDO and now through the other five regional affiliates, I have made many friends and business connections that may not have occurred if not for these volunteer organizations.

I want to “Thank” my agency the Washington State Department of Agriculture (WSDA) and my Assistant Director Kirk Robinson who have supported me throughout this year as AFDO’s President and I give special acknowledgement to Daniel Maxson who works with me at WSDA for his ideas and encouragement to apply for the FDA Rapid Response Team Cooperative Agreement and other agreements that have been awarded to WSDA. Those efforts are really helping my agency work to build better capacity and capability with our state’s food safety system.

A huge “Thank you” goes out to all of the AFDO Board members and advisors and to the AFDO office staff who have endured a number of challenges and changes throughout this past year. AFDO has exceptional staff who work really hard to help the organization’s membership and make this organization shine. They also make it look easy but I know it is a hard job. A big “kudos” to the conference planning committee for pulling off another successful conference here in Louisville, KY.

Although he is not here today, I want to say “Thank you” to my husband Bill for being so encouraging and supportive for my participation in volunteer organizations and especially my participation in AFDO and WAFDO.

Integration is a state of mind.

- Be an active participant in making changes and integration will occur
- AFDO planted the seeds of influence and integration back in 1896 and 1998.
- Think - AFDO Globally – Regional AFDO Affiliates, Locally”
- Be involved

Thank you.

**Glenn W. Kilpatrick Address**  
**Joseph W. Reardon**  
**Assistant Commissioner of Consumer Protection**  
**NC Department of Agriculture & Consumer Services**  
**AFDO 117<sup>th</sup> Annual Educational Conference**  
**Louisville, KY -- June 9, 2013**

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Thank you.

It is a tremendous honor to speak today and present the Glenn W. Kilpatrick address. As I prepared for this presentation I took a look back through the recent presentations and I know that I follow some illustrious leaders and pioneers in the regulatory world: Deb Autor, David Acheson, Jeff Farrar and Mike Taylor. Not easy acts to follow, I can assure you.

And it is a special honor to present here in Louisville, KY, a city that is home to many such illustrious leaders. When George Rogers Clark founded Louisville in 1778 he likely had no idea that this beautiful city would be home to leaders such as Thomas Edison and President Lincoln who was born in LaRue County-just down the road from Louisville. And Louisville is also the home of some of our biggest sport traditions. Louisville gave the world three time world heavy weight boxing champion Muhammed Ali, the Louisville slugger and the Kentucky derby. Kentucky has a long history of leaders and pioneers that include Daniel Boone, Kit Carson and James Bowie, not to mention the McCoy family of Hatfield and McCoy fame. That spirit of leaders, pioneers and innovators continues in Kentucky today.

I would like to thank the AFDO Board for the opportunity to present the Kilpatrick address at this, the 117<sup>th</sup> Annual Education Conference. It is only through the collaborative efforts of associations such as AFDO that we will build consensus and develop the uniformity necessary for national integrated food, feed, drug and medical device safety systems. Through meetings such as AFDO's Annual Education Conference and all of the AFDO affiliate meetings; Federal, State and local regulators come together to share the challenges and best practices in the ongoing process of optimizing regulatory systems to better protect public health. It is an honor to be a part of this meeting.

And an honor to follow in the tradition that Glenn Kilpatrick set in place many years ago.

Glenn W. Kilpatrick was a champion of integration and understood the challenges we face as regulators. He dedicated his career to developing initiatives that foster mutual understanding among Federal, State and Local regulators. Mr. Kilpatrick's career included service to our country in the Army Air Corps as well as a long career working in both Federal and State regulatory programs. He was a visionary that understood the importance of integration and the value of communication, collaboration and mutual reliance to maximize utilization of both Federal and State resources to protect public health. Mr. Kilpatrick developed the state contract program, an institution that served as the basis for federal state integration; it is still in place 30 years later. Likewise, Mr. Kilpatrick was an innovator that recognized the importance of information sharing and

promoted commissioning of State officials.

And the theme of the AFDO Annual Conference this year is a testimony to the important work that Mr. Kilpatrick started and we all continue every day: "Implementing the Integrated Food, Drug and Medical Device Safety system."

Which brings us to the topic of integration. In 2013, what does integration mean? Is it mutual reliance on inspection, compliance, enforcement and laboratory functions? Does it cover domestic and overseas operations? Does it include Federal, state, county, local regulatory agencies? Does it incorporate food safety, defense and food security issues?

In short, yes, integration includes all of that.

In the simplest sense, integration, per Webster, is the act or process or an instance of integrating as incorporation as equals into society or an organization of individuals of different groups.

By no means is integration a new concept. As we see from the work of Glenn Kilpatrick, the concepts of an integrated food safety system were being developed and implemented back in the 70's. Under the Retail, Dairy and Shellfish cooperative programs, FDA has historically relied entirely on State and local inspection regulatory agencies to ensure the safety of products manufactured or sold under those programs. To these programs integration is nothing new.

And the efforts initiated back in the 70's continue on today with initiatives such as the Partnership for Food Protection (PFP). "The purpose of the PFP is to bring federal, state, local, territorial and tribal representatives with expertise in food, feed, epidemiology, laboratory, animal health, environment and public health together to develop an Integrated Food Safety System (IFSS)." And in 2011, the passage of the Food Safety Modernization Act formalized the concept of an integrated food safety system with requirements to utilize other regulatory resources to meet federally mandated inspection frequencies.

Equally important to the success of integration is the need for consistent financial support for State and local programs. In the current budgetary environment of furloughs and sequestration, the need to continue support to ensure the growth and development of state and local programs is imperative. Providing funding through grants and cooperative agreements allows these programs to build their capacity and capability to conduct inspections, develop rapid response capability, build recall capacity and achieve ISO accreditation. In FY12, FDA provided approximately 40M in funding through grants and cooperative agreements to State and local programs to achieve this growth. Continuation of this funding is a critical component of developing integrated systems.

Through integration we maximize the utilization of all resources to enhance our public service and collective mission of protecting public health. Our efforts in integration must not only include our State and local partners but also our regulatory partners overseas. Our food supply is increasingly global; one in six products consumed in the



United States in 2011 was sourced from abroad. Currently the US imports 80% of seafood products, 50% of fresh fruit and 20% of fresh vegetable products. Imports of FDA regulated products have doubled since 2002.

And the scope of integration is not limited to food safety but also includes food security. In 2011, 15% of households in the United States were food insecure. These households lacked consistent access to food at some time during the year and this placed members of these households at elevated risk for health and developmental issues. This 15% of households translates into approximately 50 million people. In 2011, 50 million people in the United States did not have consistent access to food. The U.S. population is assumed to grow by about 50 million, from 281.4 million in 2000 to 331.9 million in 2020. A child with an empty stomach will not be able to learn. We can do better!

This increase in population will obviously result in an increased demand for safe food products, both domestic and imported. As the demands on industry and agriculture grow, so will the demands on the regulatory systems to ensure the safety of these products. In 2008, the AFDO State Food Safety Resource Survey showed that 4.6M inspections were conducted by combined Federal and State agencies with 2.4M of the inspections conducted by State and local agencies. In order to meet the increasing demands of population growth, we must increasingly rely on the combined inspectional resources of all regulatory agencies. Without an integrated food safety system we will fail in our ability to ensure the safety of these products. We must work smarter with the resources that we have.

In order to successfully integrate our programs, we must be leaders. And as leaders we must acknowledge that we will occasionally fail. General Stanley McChrystal, four star general and former commander of the United States and International Forces in Afghanistan, wisely said: "Leaders can let you fail and yet not let you be a failure". We all must listen, learn and occasionally fail but avoid the trap of confusing that with failure. We will make mistakes but we must learn from them and utilize the mistake for what it is, an opportunity for improvement. As Douglas MacArthur said, "A true leader has the confidence to stand alone, the courage to make tough decisions, and the compassion to listen to the needs of others. He does not set out to be a leader, but becomes one by the equality of his actions and the integrity of his intent."

Margaret Heffernan, an executive with BBC radio, noted during a recent talk the importance of recognizing differences and using constructive conflict to pursue innovation. In her talk she spoke to embracing inherent differences rather than constantly seeking out that which is familiar. We are conditioned from a very young age to surround ourselves with that which is familiar, those people, ideas and concepts that don't challenge the conventional wisdom or group think on which we base our conclusions. But, if we invest the time and effort into developing strong relationships, we can utilize constructive conflict as a means to improve our systems. Most big catastrophes come from obvious information that was just not acknowledged. The information was right there in front of us but we were willfully blind to it. If we avoid all conflict, if we are afraid of making mistakes then we will lose our greatest opportunities to learn, to grow and to change our thought processes.

As we move forward and measure our success in integration, we must judge our success

not by the mere policies that we put in place but rather by our cumulative work. We should judge our success not on our words but our actions, by what we have accomplished and the lives we have impacted.

We must understand and appreciate the impact of our role in public health. There is no greater honor, no greater burden than the responsibility that we bear in our role to protect public health. In many cases we are the last intervention between the public and an unsafe product. Our actions can protect children, the elderly and the unborn from terrible illness and even death. In many cases we may never know these people or meet them in person but each and every one is a neighbor, a teacher, a parent, a friend or a beloved family member to someone. And it is our duty to do all we can to protect these people; those that we know and those that we will never meet.

And with that I challenge each one of you to re-examine your role in protecting public health, to re-examine your role as a leader and a regulator and the impact that you have on someone's life every day. To consider those people affected by these decisions we make every day. And, often more importantly, those people affected by the decisions not made.

We must challenge ourselves to consider not only what is familiar to us but also that which is different and outside of our routine. We must ensure that we do not develop selective blindness that prevents us from seeing the obvious. For it is this type of complacency that will forever impede our ability to develop a nationally integrated regulatory system. And our failure to develop this integrated regulatory system will impact the lives of thousands of consumers every day. "Men make history and not the other way around. In periods where there is no leadership, society stands still. Progress occurs when courageous, skillful leaders seize the opportunity to change things for the better." —President Harry S. Truman. It is imperative that we do not fail in this endeavor. I challenge you to be that leader.

The road untraveled is far harder but the rewards are far greater if we persevere in our mission to continually improve our processes to protect public health. To seek innovative solutions through constructive conflict, to challenge us to never accept anything less than the optimal solution. The treasures of tomorrow are found beneath the work of today and, as we work toward tomorrow, we must strive for the best work we can possibly do today. As President Lincoln said, "Adhere to your purpose and you will soon feel as well as you ever did. On the contrary, if you falter, and give up, you will lose the power of keeping any resolution, and will regret it all your life."

Remember Good is an enemy of Greatness. If you settle for Good, you will never be Great. Let us strive for Greatness in all we do!

Thank you again for this opportunity.

**FDA Keynote**  
**Michael R. Taylor**  
**Deputy Commissioner for Foods and Veterinary Medicine**  
**U.S. Food and Drug Administration**  
**AFDO 117<sup>th</sup> Annual Educational Conference**  
**Louisville, KY -- June 10, 2013**

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*(transcribed)*

Thank you Stan and good morning everybody. It is great to be here. You know I think that may be the same introduction that we used last year; I promise you that if I'm asked I'll be here next year, and I promise you there'll be a different introduction because I'm getting a little bored with it myself.

This is my first time in Louisville. That's astounding to me, that at this advanced stage of my life I've never been to Louisville, Kentucky. There's a horse race here, I gather, that happens, and I know people probably come here for that. There's actually, I gather, a pretty decent college basketball team in town. The really important thing, of course, is that the Louisville Bats play here; we flew in last night over the river and it was a clear and beautiful view of the ballpark, and I'll just register my intense jealousy that I feel for all of you who are going to the ballgame tonight, it should be a lot of fun. You know, I think people who are not acculturated to baseball and the central place that it plays in our country might think that the Louisville Bats are named after a flying rodent, and we know of course that this is named after the Louisville slugger, the iconic instrument of baseball that's made here.

But actually, it's a no-brainer for me to come here, not for all those things but for this meeting and to be with all of you and I appreciate Claudia and Joe having me here, the AFDO board, and all of you for being here. This meeting is a time when I think we all come to basically renew our common causes, the things we work on together throughout the year and throughout the years, and we come here to renew the commitment to those causes and do work that will help advance those causes. I am focused on food safety. I know that the program and the organization goes beyond the food side of FDA, and I respect and value all of that. But I'm of course focused on our common causes around building a modern preventive food safety system, in particular building a national integrated food safety system to fulfill the vision of public health prevention as the foundation, the bulwark for our food safety system. And so it's just great for me to come and voice my continued commitment to those common causes that we have.

I think the place we are right now with FSMA implementation makes this a particularly opportune time to be here, to be together, and to have the continuing dialogue. And I'm going to talk a little bit about the proposed rules and where we are with that. There is a shift that's so strong and so clear that's going on in the mindset of people in the community. It's yes, we've got to get the rules right, but how are we going to implement them? How are we going to operationalize these? What is it going to mean in practice for the incredible diversity of enterprises that are affected by the rules and for us, all of us who have a role in making this come to life. So I want to talk a little bit,

as well, about where we are with implementation planning, how we need to work together, work we're all doing, I know, to plan how we operationalize this FSMA model of prevention. And then I want to touch a little bit just on a few thoughts on what it means to be building genuine partnership and I know that's the continuing quest that is embodied in AFDO, among the states, with private sector stakeholders, and certainly in working with us. And that's not the easiest part of this whole enterprise, but it's as important as anything that is going on with rules and the actual work we do. How do we build that genuine partnership?

So let me just start with a few thoughts about the proposed rules, where we are in the process, and some of the challenges that I think we have yet before us during this rulemaking phase, during this comment period. We must be sure that people understand what we're proposing, feel that they've had a full chance to have input, and that we can get a rulemaking process, a rulemaking record together, that gets us to the right rules at the end of the day.

But, you know, there's no question that by issuing the preventive controls proposal and the produce safety proposal in January, we really did launch FSMA in a serious way. Laid out in the splendor of a thousand or more pages, is our best thinking about what it would mean to implement these mandates of FSMA on the farm for the first time, setting standards for prevention in processing facilities. We would not be setting standards for prevention for the first time but applying those standards comprehensively across the whole food system, across all of its diversity. I think for us, the central challenge of the rulemaking, whether it's for produce or for preventive controls, is seen figuring out how we can develop rules that do work effectively, efficiently, for food safety across that whole diversity of operations, and do it in a way that is practical so that in each setting in which these rules apply, the rules that we're developing actually make a practical difference for food safety.

We can't issue rules that are abstractions, that then apply one size fits all approaches to this diversity of operations. That won't fly, that's not good for food safety, that's not the best use of resources, it doesn't work for the industries that we regulate. And so for us, that effort to develop rules that are adaptable to that diversity, I think is really the central challenge that we've got. The advantage, what makes all of this possible, of course, is that we're not, in issuing these rules and implementing FSMA, starting from scratch. We've got the history in the processing setting, HACCP, of preventive controls, of industry itself having developed the modern systematic approach to process control for food safety. And so we draw on that. And that will hugely inform the way in which we implement the preventive controls requirements. And even in the produce world, where again I think this is the most challenging – I've said this before, and it remains true, perhaps it gets truer every day – rulemaking that I've ever been involved in, but again we're not starting from scratch.

This builds on good agricultural practices that have developed over years, it builds on the scientific understanding of what are the basic pathways of contamination, and the challenge is taking that understanding that's evolved over the years and converting it into rules, into something that's actually enforceable and creates the accountability for prevention that FSMA is all about. And so that's the work that's underway, that's the work we're doing, as we go through the rulemaking process. We're pleased to have

extended the comment periods for 120 days beyond the mid-May initial comment period. We now have comment periods for these two rules that will run through September, mid-September, September 16<sup>th</sup>. We want to take full advantage of that time to continue the dialogue that we've started and that I think has been robust and helpful to us so far, but that's still ongoing.

I know that AFDO and NASDA are working together to develop comments that would bring together the perspective and expertise of our state and local partners into the rulemaking process, and that's fantastic. We want to work with the team that's doing that, and answer clarifying questions about what we're actually proposing to help support that comment process and so that, again, will be all to the good. That's a necessary part of getting information into the rulemaking record that can then be overtly relied upon in shaping the final rules. It does not replace and should be seen as complementing the face-to-face dialogue we can have as we go through this process to answer questions and be in a continuous learning mode with each other as we develop the regulations.

You know, one thing that is clear to us particularly on the produce side is how critical the outreach to our communities is, and certainly the folks represented here, but you know, the produce sector is just a remarkable part of our food system and food economy. I have to confess that when I came back to FDA, I was not all that close to it. I hadn't really spent time in the produce arena. But I've had a deep immersion in this part of our food system through travelling and going on farm visits and having, I don't know how many, listening sessions and meetings, talking to growers of all scales, in all parts of the country. Folks who are out there producing fresh produce that we all want to have in abundance, and be really accessible to our consumers. And you know, it's an inspiring thing to do, to kind of get close to a part of the food system that you haven't seen before. I mean, these are people who care deeply about what they're doing, and I say this without regard to scale or country or location, whether it's the biggest growers out in Salinas, or the small produce operations in North Carolina, these are people who care about what they're doing, they're passionate about what they're doing, they care about food safety, and they want to be able to provide safe product to their consumers.

And so it's been actually very gratifying to me to have that experience, to be out there, to have that engagement. And I think that engagement has so far stood us in good stead, I think we've done a lot of outreach to that community and answered a lot of questions. We know we've got a lot more to do to answer those questions, and that's one reason why we extended the comment period. There's a lot of anxiety, I think it's fair to say, among some sectors in the produce community, about how the rules will affect them, and we just think it's absolutely critical that we answer those questions so people are clear about what we're actually proposing so that they can provide comments that are informed and that will help us get to the right final rule that really does work in the right practical way across that diversity.

And so while we've done a fair amount of outreach, I think you'll see evidence over the next weeks and months of us really stepping that up, and getting out some clarifying messages, getting people to understand the basics of who's in, and who's out, and how we envision these rules actually applying and what we mean when we say that they're adaptable to diversity, and are not one size fits all. We received a letter last week, or

the week before last, from the New England Congressional delegation inviting us to come up to New England to have further meetings with farm growers up there. We're eager to do that. I think that they were suggesting one meeting, I've suggested well why don't we go to all those states – I've probably just overcommitted my staff to something they're not so sure that they can pull off logistically; but the point is, you know, this is extremely valuable to us if people want to engage us on these rules and we are all up for it.

We're going to be doing that, you know, in a very substantial and noticeable way in the coming weeks and months. And so we think there are some basic points that people ought to get, particularly the smaller growers who are concerned about feasibility. One of the realities of our proposal, the way it's crafted through what we propose and what Congress mandated, is that a very large percentage of produce operations are in fact exempt; 79% of the 190,000 produce farms in this country are not subject to the rule. It's the accommodation of what the so-called Tester Amendment did, which exempted farms with sales up to 500,000 provided half of those sales are directed to consumer or retail. That takes out some 75,000 farms, about 40% of the produce operations in the country. We proposed our own, what we considered the minimum threshold of sales below which we felt it was just not feasible for us to extend federal regulation. So for farms with sales less than \$25,000, we proposed to exempt them with our own inherent authority to be sure that we're putting out rules that are practical. That takes out another 34,000 farms, about 18%.

So we're still covering a huge, huge majority of the production, because of the way production is distributed, but we need to assure the smaller growers that many of them are not covered by the rule. Which doesn't mean they're not covered by food safety; it doesn't mean they're not part of the food safety system. They're still subject to all the longstanding adulteration requirements; obviously they're subject to the remedies if there's a problem; and they're a community that we ought to be working with just as vigorously as we're working with those who are subject to the rules, to support their progress toward implementation of good agricultural practices, or whatever local requirements there may be. It's not that they're not in the fold in our eyes, as part of a positive approach to food safety. But we need to allay concerns about where the reach of federal regulation goes and where it stops and those are important distinctions.

We're also going to be making clear the things that we've done to minimize costs, to be sure that the rules are targeted where they really matter. So whether it's the water and raw manure standards that for the first time have numerical federal standards about how you ensure the safety, the appropriate quality of water applied to crops; well of course, those standards only apply if the water's applied directly to the edible portion of the crop. It doesn't apply and a lot of people, I don't think got this on their first pass through the rules that numerical standard for water quality does not apply to water that's used in drip irrigation or other alternative approaches to using water in agriculture. Likewise, the raw manure standard.

We also are proposing to accept alternative approaches. Even if you are subject to that standard, you can show that in your region, for climactic or other reasons, that you get die-off of pathogens between application of water and harvest such that you can get the same level of safety even if you don't comply with the numerical water quality standard.

That's another flexibility built in. Congress has also established a variance procedure, so that a state can, if there's a commodity that's being produced under certain conditions in a certain state – I'll use Washington State as we have Claudia here and her leadership role. How do you recognize that there are practices going on in the apple industry, for example, in the northwest, where the combination of things that are being done in the management of water and other things sanitizing product results in a safe product that may or may not be produced in a way that precisely complies with what we've proposed but gets the same level of safety? Well, Congress has said, we could recognize those practices through a variance management of states, or through the alternative process that we've set up.

So we want to be sure that we're clear about what our rules require and what they don't require, so that if folks have a certain level of anxiety, it can be based on what we're actually proposing. Then let's deal, let's get the comments that enable us to address the legitimate issues that people have. At the end of the day, what we care about is that what we are proposing will make a practical difference for food safety and be feasible, workable across the diversity of the food system.

So comments that point out how it is that something we're proposing does not make a practical difference for food safety, and therefore is imposing costs that are not justified, are comments that we are eager to get. And we need to have that dialogue with the community. So we've got a lot of work ahead to get the rules right. We're eager, again, to get comments from AFDO institutionally, from states individually if you're so inclined, and however we can have the dialogue that enables our rulemaking to benefit from the wisdom that you bring to bear, we want to do that in a very serious way. So that's enough on the proposed rules; happy to take questions about any aspect of that.

Let me just say a couple things about what we're doing in planning implementation and thinking through the issues of operationally, how do we actually bring this to life? And again, we all know the importance of this. Food safety is affected not by what we write down on a piece of paper in our rules, or even our guidance's, it's what actually happens on the ground. It's what people in the industry are doing every day to make safe food, it's what we do in our government oversight role to be sure that the preventive standards that we've agreed are the appropriate ones are in fact being implemented; it's that front line activity that makes food safe or not. So that's why it makes all the sense in the world for the implementation phase of FSMA to be front of mind for people, and why it's far from too soon for us to be working on this in a serious way.

We've developed some ideas about what the operational strategy for FSMA implementation should look like, in terms of how we conduct inspection, how we carry out compliance activity, and how we work in partnership with our state and local colleagues. And I think all of these are just critical topics that we have to think through and be open to completely new approaches to implement this law successfully. On the inspection front, we now have for the first time an inspection frequency mandate, but we see the change that is driven by FSMA going way beyond, when we think about how we conduct inspection, going way beyond meeting that inspection frequency mandated. And in fact I think that in our model, we don't want to be tied to the inspection frequency mandate in the law as sort of a ceiling above which we don't go. It's a floor.

We need more presence, we collectively need more presence out there at the front line fostering compliance, not be tied to a statutory mandate that again, in my mind, creates a floor that we need to work well above. But it's not just a matter of numbers.

It's what we do when we go in and inspect. And this is where again I think we all realize that when we have a confidence in food facilities, a confidence in the preventive controls framework, we've got to be prepared, as those in government overseeing this, to understand preventive controls, to understand a systems approach to food safety, to be able to look at what's going on in a facility and make a judgment about whether this is a facility that is operating in a way that is going to be effective in preventing problems and in managing the safety of the product coming out of that facility. So we're looking at ways to change how we do inspections, probably a training matter as all of you know in terms of preventive controls and understanding systems. But it's also, how do we target our efforts? How do we be sure that we can make assessments efficiently of facilities that need more inspection time vs. those who perhaps need less inspection time because of their demonstrated performance and ability to provide assurances that they're in compliance on a consistent basis?

Lots of room for improving the targeting and thus effectiveness of inspection, but also the efficiency of the use of our inspection resources because the more efficient we can be, the more public health bang we can get for the buck. We don't want to be duplicating effort between us and our state and local counterparts, we don't want to be wasting our own time and energy in the inspections that we do. So there's a huge focus on how we revamp inspection.

Now compliance is its own, critical area in which we have a great opportunity to innovate in implementing this law. And I'm really basing that to a very large extent on the fact that we now have our administrative enforcement tools, administrative detention, the ability to suspend registration facilities. They give us the power, some of which states and locals have had for a long time, to act administratively in real time when we observe a facility not operating in a way that's effective in prevention, that's operating in a way that is potentially putting consumers at risk. We need to be able to work in real time to take action in those cases. The inspection and our presence on the front line should incentivize compliance, and support farms in complying, but when there's a problem with compliance putting people at risk, you need to be able to act in real time, act preventively to protect consumers. And so we're rethinking the compliance strategy and how we use those tools and how we streamline our own decision-making internally in order to use administrative tools in real time. And this is a challenge for an agency of our size and our history and our established ways of working. But there's a huge commitment within the leadership to work through how we can streamline our own work internally to make good on the strength and compliance tools that we have under FSMA. We've got to deal with all of those issues.

We've established the FSMA Operational Teams, that we're calling them, which consists of three teams, one addressing the produce rule, one addressing implementation of preventive controls rule, the third addressing the implementation of the import rule. These teams are cutting across organizational lines within FDA, headquarters, field, centers, front line people, but also include representatives of the states. And so Patrick Kennelly from California, Ernest Julian from Rhode Island, Steve Stich from New York are representing AFDO and the states on these teams. And there will be a lot of



engagement as we go down through this process to bring the state perspective into this planning that we're doing internally to carry forward implementation of FSMA.

These FSMA Operational Teams, for lack of a better acronym and term we'll plug in "FOT"—out there I see Sarah knows the term quite well—These teams need to be and are closely connected with the Partnership for Food Protection effort, which has been of course the central institutional set of arrangements for us to work together, and to build the partnership to implement these rules. So there's a huge effort geared up, a lot of folks working hard, again it's all looking ahead, down the road, and even though it is a few years down the road before we'll have rules that are in effect and enforceable, we need to be doing this work together and I just want to assure you that we're certainly focused in a very serious way on that within FDA. Cutting across all of that work—those FSMA operational teams, and everything I've talked about—of course, is this fundamental idea of partnership.

And, you know, the partnership concept cuts across everything we're doing in FSMA, embraces our partnership with state and local governments, but is also about how we work within FDA in partnership. How we work with foreign governments in partnership, how we work with the food industry in partnership. We know on that front that all the guidance that we need to develop and put out, to articulate how our rules, will inherently be general at a certain level. How they apply in particular circumstances, particular processing operations, we can't do that without the expertise and the engagement of the food industry. And so partnership abounds throughout this, but there is no more fundamental partnership for ensuring the success of FSMA than the one that we have with our state and local counterparts. And I just want to be here and I will be here next year if asked and the year after that just to affirm the commitment to that, the understanding that we have about how central that is.

There's just no way that we could successfully implement this law if we don't work in close partnership. You know, some of that happens because we have these FOT teams, we have the Partnership for Food Protection, and we've got committees working on the operational plans and procedures and working on defining roles and responsibilities between us and throughout the system and that's all critical work. That's sort of the intellectual side of building this partnership, getting that apparatus squared away and in place. But I think we all know that the real challenge of building this partnership is not the intellectual side of it, but it's sort of the human and at some level emotional side of it.

You know, we have to do this in a way that truly is based on mutual understanding. And again, at one level it's intellectual understanding of as a practical matter why we need to be doing this work, but it's also understanding of each other and the roles that we play and it's building that respect and trust that is the foundation for real partnership. I think a lot of that exists now, I think that we've made progress on that front, but I think we all know that that's a continuing work in progress. You know, we're talking about fifty states, thousands of localities, you're talking about an agency, FDA, that has a long history and it's a big complex organization.

We're all coming, as much as we've been working together for years, we're all coming from different places towards this common partnership approach to doing our work

together. So I think we have to just be real and accepting of the human dimension of this and what it takes to be successful to build partnership in that context. It certainly takes, at a leadership level from folks like me, and folks in this room, it takes a commitment to it, it takes effort to sustain just sweat equity put into the work. I think it also requires each of us sort of putting ourselves in the other person's shoes, to some extent, and doing the work to understand why it is that that person is doing the work that way, responding in that way. Why does this person over here has established ways of doing things? Let's invest the effort to really fully understand where we're all coming from. I think that's how, since we all have the same goal, food safety, we all have the same goal, again, intellectually, of building a national integrated system, let's invest as much effort in the human side of building the understanding, building the mutual respect and trust that is clearly going to be essential for success. I think if we do that, nothing can stop us; I think if we don't invest in that human side of things, I think there'll be lots of difficult meetings for a long time. I think we have a lot of work to do for a long time, but I think we all aspire to do it in a way that really does feel like genuine partnership, a common team.

And as I say, I think that enormous progress has been made. I think the Joe Corby's of the world, and others who've been at this for a long time, I hope feel, and they should certainly feel, that the efforts that have been put into the Partnership for Food Protection and all that's come before has laid the foundation. If we were starting from scratch, we'd be doomed, but we've got a great foundation. And I think we've made real progress. But we're all still in learning mode; I think we need to stay in a learning mode, and we just need to keep at it. And I think that's the way in which this can succeed; that's certainly my motivation and frame of mind. I don't know where you're meeting next year and I plan to be here, or there, if you invite me, and I really look forward to continuing to build our partnership together.

Thank you very much.

**Health Canada Keynote**  
**Ward Chickoski, Regional Director General**  
**Health Canada, Health Canada Prairie Region**  
**AFDO 117<sup>th</sup> Annual Educational Conference**  
**Louisville, KY -- June 10, 2013**

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*(transcribed)*

Good morning everyone, I am pleased to be here in beautiful and historic Louisville, Kentucky; although I didn't see any hockey arenas when I was landing, I did have a chance to see the stadium for the Louisville Bats so appreciate the importance baseball plays in this community and humbled by the fact that there are no Canadian teams currently in the hockey playoffs. My name is Ward Chickoski, and I am the Regional Director General, for Health Canada's Prairie Region, which spans the provinces of Manitoba, Saskatchewan, and Alberta, and also provides service to Canada's Northern Territories of Nunavut, the Yukon. It is a pleasure to present to you today on behalf of Health Canada.

Health Canada's participation in AFDO, and its regional affiliate organizations has been both long-standing and fruitful. We are honored to provide a keynote address again at this year's annual conference. These events are important opportunities to share and learn from the valuable experiences of leaders in food and health product safety, and for discussions on how we can continue to improve the way we collaborate. And many of you may know my colleague and one of my team members Robert Scales, who is our primary representative at ADFO, and who has done an exceptional job in making sure that we're well represented at these sessions. He is also the Chair of the International and Government Relations Committee with Mark Roh, so we're very pleased to be able to present today. He was not able to join me at this year's session but I'd like to send you his best wishes and greetings.

I'd like to take this opportunity to give you an update from Health Canada and highlight a few of our recent and more prominent initiatives that support our commitment to ongoing safety of food and health products. First I'd like to give you a bit of an overview of Health Canada responsibilities.

**Overview of Health Canada's Responsibilities**

Health Canada has a broad mandate which includes ensuring that the food Canadians' eat is safe, healthy and nutritious, and that the health products they use are safe and effective. In addition to food and drugs, we are responsible for regulating medical devices, natural health products, veterinary medicines, genetic therapies and biological products such as vaccines. We provide information to Canadians to assist them in making healthy decisions, and provide health services to First Nations and Inuit people. We also work with the provinces and territories to ensure our health care system serves the needs of Canadians.

With respect to food, we share the responsibility for food policy and programs with other federal departments, and with provincial, territorial and municipal governments,

all of whom have important roles to play. At the federal level, we work closely with the Canadian Food Inspection Agency, or CFIA, who takes the lead in enforcing the provisions under the Food and Drugs Act and the Food and Drug regulations, and for managing emergencies involving food safety, animal health, and plant protection. We support the CFIA by performing health risk assessments, and by collaborating on research into detection methods for priority threats to the food supply.

Pesticide regulation also has a place in Health Canada's role in food safety. The Pest Management Regulatory Agency of Health Canada is responsible for approving pesticides and conditions of their use, and for setting Maximum Residue Limits for pesticides in food. The Pesticide Compliance Program delivered through Health Canada's regional staff along with provincial regulators, ensure pesticides are used appropriately by growers and help producers ensure a safe food supply by following good agricultural and pest management practices, including adhering to label directions.

In Health Canada, the Regions (part of the Regions and Programs Bureau) are the delivery arm for our organization, managing the delivery of our regulatory, scientific, and laboratory based programs and services, and doing so in partnership with Health Canada's regulatory branches. This model allows us to maximize our horizontal perspective, as well as gather and share regional and pan-regional intelligence to inform innovation in program delivery and design, and to ensure regional perspectives in the development of national policy.

### **Highlight of initiatives and priorities related to health products and food**

Given Health Canada's vast mandate and our commitment to help Canadians maintain and improve their health, we never have a shortage of work to do or goals to achieve. I'm happy to tell you about some of the initiatives we are moving forward on in the area of health products and food.

#### **Natural Health Products**

We are continuously working to ensure Canadians have access to natural health products that are safe, effective and of high quality.

Natural health product (or NHP) is a term used in Canada to refer to a group of health products including:

- Vitamin and mineral supplements
- Herbal remedies and other plant-based health products
- Traditional medicines (such as traditional Chinese medicines)
- Homeopathic medicines
- Fatty acids (such as omega 3, 6 and 9)
- Probiotics
- Some personal care products such as toothpaste

Most of these products are known as "dietary supplements" in the US. As of January 2006, all manufacturers, packagers, labelers and importers of natural health products

were required to hold a valid Site License for the purpose of conducting any one of these activities.

Natural health products are regulated under their own specific regulations, the Natural Health Products Regulations, which take into account the unique nature and properties of these products. Since 2004, Health Canada has authorized over 60 000 NHPs for sale (compared with about 7 000 authorized prescription medications).

As part of our ongoing commitment to continuous improvement, the Government of Canada has developed a new approach to Natural health products. We have heard from stakeholders, consumers, and parliamentarians that there is a need for increased access to products while maintaining consumer safety, and for the reduction of unnecessary administrative burden for companies trying to bring safe products to market.

With respect to compliance and enforcement of the NHP regulations, Health Canada is continuing an emphasis on compliance promotion during the ongoing transition period. Once the transition period ends on September 1, 2014, products without a Product License (either a Natural Product Number (NPN) or a Homeopathic Medicine Number (DIN-HM)) should not be available for sale or imported for sale into Canada. At that point, Health Canada will continue to employ a risk-based approach to their compliance and enforcement activities.

### Food Policy Initiatives

When it comes to food labeling, Health Canada and the Canadian Food Inspection Agency play joint roles: Health Canada establishes policies, sets standards and provides advice and information on the safety and nutritional value of food; the Canadian Food Inspection Agency provides all federal inspection services related to food and enforces the food safety and nutritional quality standards established by Health Canada.

In the regions, our Food Policy Liaison officers work on key policy files, both working on national guidelines, and connecting with key regional stakeholders to ensure our policy documents represent the diverse views of stakeholders.

### Health Canada GMP Inspection Program

I would also like to share with you some activities in our Inspectorate Program that relate to the quality assurance for drug products. Good Manufacturing Practices (or GMPs) are the part of quality assurance that ensures that drugs are consistently produced and controlled in such a way as to meet the quality standards appropriate to their intended use. Part of our Inspectorate program is to conduct inspections of establishments that are involved in activities covered by the Establishment Licensing framework. These inspections are conducted to verify compliance with GMPs, which is a requirement for the issuance of an establishment license.

Health Canada conducted a review of its GMPs Inspection Program for drug establishments in an effort to make the program more risk-based. The findings of this review resulted in 28 recommendations, which have been implemented since 2010 in a staggered approach.

The extension of GMPs to Active Pharmaceutical Ingredients (or APIs) has increasingly been recognized as a necessary element in ensuring the overall quality and consistency of marketed drug products.

In May 2013, Canada's Food and Drug Regulations were updated to extend the requirements for Good Manufacturing Practices to active ingredients used in pharmaceutical drugs. These amendments will come into force in the fall of this year. We believe this is an important action to improve the safety of Canada's pharmaceutical drug supply.

These requirements will apply to all active ingredient manufacturers, packagers, labelers and importers. We have begun working with Canadian companies to help them better understand their new responsibilities in manufacturing drugs.

### **Responding to the challenges facing Health Canada**

Both of our countries are constantly faced with products that challenge our regulatory frameworks and processes, such as energy drinks, caffeinated foods, compounding and admixing, and combination drug-devices.

Canada's regulatory systems for food, health and consumer products have served Canadians well over the years. However, trends such as advances in science and technology, globalization and changing consumer demands are driving the need for regulatory modernization and international cooperation to help us meet these challenges.

### **Regulatory Modernization**

Regulatory modernization is one of the key priorities for Health Canada. We are currently working on a Regulatory Roadmap for Health Products and Food that provides a vision of transformation: where we are, where we are going, and how we are going to get there. As a strategy, the Roadmap provides the vision to transform nearly a dozen current frameworks for food and health products that are of various ages and regulatory approaches into an efficient, transparent, and comprehensively aligned regulatory system that contributes directly to the safety of Canadians and the benefits they gain from food and health products.

The Roadmap lays out the way to move from the old frameworks to the new regulatory system. Modernization will require the sequencing of a number of amending initiatives, some staged in the near future and others implemented in the longer term. Early emphasis will be placed on amendments that will:

- deliver the clearest value to both Canadians and to the national health care and food safety systems; and,
- deliver the greatest efficiency. We will accomplish this by cutting through unsustainable administrative requirements or approaches, and replacing them with ones that draw upon international partnering, best practices and new technological advantages to contribute directly to the safety of food and health products.

Throughout the process of transformation, a key commitment within the Roadmap strategy is to work openly, transparently and meaningfully with Canadians, stakeholders and partners in the development, improvement and implementation of the plan for modernization.

### International Collaboration

Our Regulatory Roadmap for Health Products and Food also recognizes that international partnering is necessary to regulate food and health products in a sustainable way, given the international nature of the food and health product industries and their increasingly complicated supply chains. The Roadmap lays out the benefits of a shared global approach, and aligns with current Government of Canada initiatives to find ways to reduce and prevent regulatory barriers (such as the Regulatory Cooperation Council and the Red Tape Reduction Commission). Further promoting Health Canada's cooperation internationally will continue to be a priority, and a factor in developing the regulatory agenda going forward.

Canadian regulators and scientists have made great contributions towards the goal of greater international collaboration. Participation with international partners, through intergovernmental exchanges or forums, has resulted in the creation and adoption of standards and processes, such as the use of the Common Technical Document. Additionally, Health Canada has secured agreement from the United States Food and Drug Administration to make use of their electronic system for filing drug submissions. This important collaborative work brings efficiencies to the regulatory system, while maintaining Health Canada's ability to make independent decisions on drug submissions and enhancing the high level of oversight for the health products that Canadians consume and use.

The use of Mutual Recognition Agreements and Memoranda of Understanding has already resulted in the sharing of the global regulatory workload.

Implementation of the Roadmap will build upon these successes, converging in an even greater level of cooperation.

### Import Sector Collaboration

With globalization, millions of health products and foods are traded between countries every day. Food and health products cross all borders now, and our approach to ensure the safety and quality of these products must likewise extend beyond our own borders. This is an example of regulating that will draw upon greater international cooperation. Following the creation of the Canada-U.S. Regulatory Cooperation Council (RCC), December 7, 2011, the RCC released the Joint Action Plan on Regulatory Cooperation, which is a first step to increased regulatory cooperation between the United States and Canada.

The Single Window Initiative is one of 32 initiatives of the Action Plan, involving the movement of products across our common borders. The initiative aims to provide more efficient border processes overall. The goal of the initiative is to facilitate trade and align

regulatory approaches to protect health, safety and the environment while supporting economic growth. Health Canada has regulatory oversight in five areas where import safety is a concern. This includes health products; consumer products; radiation-emitting devices; controlled drugs and precursors; and pesticides. The Single Window Initiative provides importers with a single window to electronically submit import information in compliance with customs and government regulations and in turn connects border officials to Health Canada inspectors seamlessly, as and when required. Another good example of emerging international collaboration is Health Canada's recent experience hosting a joint routine inspection in a Canadian company with US partners. It was a concurrent 'Good Manufacturing Practice' inspection that took place in Winnipeg. By all accounts, it was a resounding success- as it was comprehensive, coordinated and very efficient! Feedback from the company was extremely positive and constructive, and we are encouraged to continue pursuing these opportunities. Since this time inspections have been observed by both parties and other work sharing opportunities have been explored with the Therapeutic Goods Agency in Australia.

There also continues to be interest and energy for face-to-face meetings between Canada and the United States around mutual border issues. Within the past year, the Prairie, Ontario, British Columbia, and Atlantic regions were engaged in a meeting involving FDA, US Border Patrol, CFIA and Health Canada's Border Integrity Unit and Canada Border Services Agency. This was also an exciting opportunity for officers to introduce themselves, describe their respective work efforts, and to exchange questions and ideas about future working relationships.

And on a slightly larger scale, the same type of exchange happened among executive level officials of FDA, CFIA and Health Canada (among others) at a meeting of Northern / Southern Border Issues, which took place in Chicago, Illinois in late October. It was a great opportunity for rich dialogue, exchange and advancement of our respective governments' agendas.

We know Canada and the US have a strong record of achievement in regulatory cooperation on which to build. Both countries are committed to working through the RCC to provide early notice of regulations with potential effects across our shared border, to strengthen the analytic basis of regulations, and to help make regulations more compatible. The US and Canada will seek, to the extent possible, to coordinate the RCC's activities with the work of the U.S.-Mexico High-Level Regulatory Cooperation Council when the three governments identify regulatory issues of common interest in North America.

Through collaboration, our international networks like AFDO provide opportunities to overcome many of the challenges we face. Health Canada has reaped great benefits from the sharing of best practices with our US counterparts through AFDO, and its regional affiliate organizations, and we see these relationships as essential to our future success in building a modern regulatory system that is more efficient and responsive to the needs of consumers.

In closing, I would like to repeat how pleased I am to have this opportunity to share the plans and activities we are employing in Canada, with particular emphasis on the work happening at the operational level in the regions.



We look forward to our continuing partnership as we explore new and innovative ways to protect the safety and quality of our food and drugs in our respective countries and across our borders throughout North America.

Once again, thank you for this opportunity to speak and meet with you this morning.

Thank you very much.

**CFIA Keynote**  
**Cameron Prince, Vice-President Inspection Modernization**  
**Canadian Food Inspection Agency**  
**AFDO 117<sup>th</sup> Annual Educational Conference**  
**Louisville, KY -- June 10, 2013**

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*(transcribed)*

Well thank you, Dawn, for that introduction. To follow up from that panel, that was extremely interesting, and I think that all of us learned quite a bit from the panel, and I think you'll see some things in my presentation as well about what's happening in Canada that are very parallel to some of the issues that were discussed at the panel that just concluded. Thanks for the invitation to speak; this is my third year that I've been giving the CFIA keynote, and I always look forward to coming here; it's a great organization, it's great to be part of this conference every year and I think it's really interesting this year that it's in Louisville, Kentucky, and I know that Louisville is, the Louisville Slugger baseball bat is an icon in Americana but I want to add to that, that some may not know that Louisville Slugger used to make hockey sticks as well, and I remember when I was fourteen years old, one of the best games I ever played, I scored a few goals, I had a Louisville Slugger hockey stick, so that's something that I'm looking forward to getting down to that museum and seeing if they've got any hockey sticks down there along with those iconic baseball bats.

Before I get started in talking about some of the exciting things that are happening with food inspection modernization in Canada, I do want to take a moment to recognize one of my colleagues and one of your colleagues and friends, Dr. Bill Teeter. Bill is with us here today and I mentioned Bill kind of got me involved in all of this and I thank him for that. He's been very, very active on the Canadian side, and building bridges, Canada to the U.S. with the various chapters, and as a board member here at AFDO as well, so I mention this because Bill's going to be retiring this fall, so it doesn't mean he won't be involved, but I think I just want to recognize his great contribution on behalf of the CFIA and the government of Canada, and I'm sure you at AFDO share that feeling.

So as I said, some very exciting things are happening, and very parallel to what we see here in the U.S. with food safety modernization. So we've been at this now for a couple of years now, really concentrated effort on modernizing food safety and inspection at CFIA, and I personally have had the privilege of being able to step out of the fray, so to speak, of operational activities, and move into a dedicated role on modernizing the inspection function – very much orientation on the front line delivery and how that will happen – and it's been a very successful, a very interesting ride for the last couple of years, and I think very successful. So in budget 2011, the federal government announced 100 million dollars over five years for the CFIA to modernize food inspection and actually there's been additional funding as recently as last week, an additional 16 million dollars was announced by Minister Ritz, our Minister of Agriculture, to add to the modernization initiative. And as we were moving along that path of modernizing inspection and trying to get that vision of what, how we would adapt to the future, lo and behold, after over a decade of efforts, we have a new consolidated food safety act called the Safe Food for Canadians Act, and that act very much parallels the FSMA Act

here; it really consolidates the food legislation. The Food and Drugs act that my colleague from Health Canada spoke about remains; it covers foods, drugs, cosmetics, etc., but the food portion is enforced by CFIA. And then our other federal acts, such as the Meat Inspection Act, the Fish Inspection Act, the Canadian Agricultural Products Act, those have all been consolidated into this new act called the Safe Food for Canadians Act. So it's a very significant event in Canada, and it very much parallels what's happening here in the U.S. We have been working on a new inspection model, I'll talk a bit about that, and the beauty of this is that with the passing of the act, we can now implement this model that we have been consulting on and finalizing over the last couple of years, so it's very fortuitous the way things have worked out in terms of timing.

As I said, all of this lines up very much with FSMA, and we've been working very closely with the FDA, and in fact we've had an advisor from the FDA working directly with us through the process. An additional part of this is some investment in training tools, IT systems, and so on, and investment in our laboratories.

Everybody that talks about food safety modernization probably has a slide something like this: the point here is that the world is changing, there are many, many factors that are driving us to change, that we can't rest on our laurels and our long and very good history in food inspection in North America, but we look at what's global trade, population growth, consumer demands, modernization by our trading partners, there's a whole bunch of things that you all know very, very well that are forcing us to change what we do. So what we've said in Canada is that we have to be able to deliver better protection for Canadians and for our markets overseas; we have to focus on prevention rather than the traditional approach, and that prevention involves control of hazards; it needs to be more transparent, and this is an area where I'll talk a bit more about, there is, definitely consumers are expecting to see more and I think it's fair to say that in many ways the U.S. is leading Canada in this regard. We see some of the things you're doing and hope to emulate some of that transparency as well. We have to be internationally consistent, international trading rules, and we need to harmonize wherever possible. And this is, I think, my own personal view, but I think when you look at the Canadian-U.S. context and the amount of trade in food that goes back and forth across the border, harmonization, whatever word you want to use, equivalence, finding better ways of doing things together, integration is a theme at this conference; I think these are the kinds of words that we need to use when we talk about being internationally consistent and finding ways to do things the same to the better good overall. We need the best tools and technology, and we need to be able to assess what we're doing in order to tell our story, to demonstrate that the inspection systems that we deliver are effective.

So just quickly, in terms of positioning CFIA in the Canadian system, we're not alone, as we are somewhat similar to FDA or very similar, and I note the many state partners and so on, we have exactly the same thing in the U.S.: provinces and territories that have significant roles in food inspection; we have federal partners, Health Canada, who sets the standards for foods and we enforce those standards, but we work very closely with Health Canada. The Public Health Agency, somewhat like CDC here, is responsible for foodborne illness outbreaks and managing those overall, although we do the recalls. Again, CFIA enforces increasing the industry role of a shift in the thinking, a greater responsibility for industry when it comes to programs, and that is – we find industry

stepping up to that challenge. And finally, consumers increasingly need to be part of all this, not only on the home-based interventions that take place in terms of cooking food and sanitation and so on, but the increasing consumer interest and that is an important area that's expanding for us at CFIA.

So the four elements, quickly, and I'll delve into these a bit further:

Number 1: Stronger food safety rules. So that's the new act, and in order for that act to come into effect, we need to produce new regulations. And those regulations will have things like importer licensing, we've had some changes to our meat manual for better notifications, I'll talk a bit more about that. Traceability for food, a very high profile issue around new rules, so that is all coming.

More effective inspection, and this is where we take the new inspection model that we have built and actually implement it; it really moves us away from that commodity-based approach that has historically for over a hundred years has been our history of meat, fish, dairy, etc., trying to break down those boundaries and deliver one food inspection program while retaining that commodity expertise where it's needed. So we need better inspection tools, better guidance documents for industry to follow, centers of expertise where we have folks that are specialists in those particular commodities to support front line inspectors, and a stronger laboratory capacity at the federal level in partnership with provincial laboratories.

And then there's the third pillar, which is a commitment to service. And although we are a regulatory organization in many regards, we also serve, in the sense that we issue export certificates on these kinds of things, so it's kind of a dual role of being the regulator and the enforcer, coming first in terms of food safety, but obviously we need to demonstrate to the regulated parties that we're fair and open. We've developed a statement of rights and services that's available on our website, that outlines the highlights of that. We have established a complaints and appeals review office, and this has been strengthened in the new act as well, with real teeth and real power.

Compliance promotion is an area where we need to look at how small business can adapt to these changes that are coming, and we look at many of the models here in the U.S. with the alliances and so on as good examples of how to proceed there. Service standards, and of course the unavoidable discussion about user fees that is coming, certainly we see an appetite for where there's private good to be charging an inspection fee. And we need to build our IT systems to better support all of this.

And the fourth pillar is really about transparency, more information for consumers, and improved online tools. We need to be able to have electronic pipelines so that there's better access to our programs and to our services and back to industry and consumers. Just to go through these pillars fairly quickly, under stronger food safety rules, as I said, the Safe Food for Canadians Act, it has tougher penalties for activities that put health and safety at risk, significantly tougher penalties. It provides much better control over imports, allows for a food traceability program, and one of our constant criticisms is that we're not consistent as we deliver inspection programs across the country and there are measures within this act that mandate a more consistent approach across all food commodities and as we deliver on the front line. So we are working on new food

regulations right now, much as the U.S.'s FDA is publishing the various rules and so on, we're in that very same process, maybe a little bit behind in that our act came about a year or so later, but we do propose to have new food regulations, at least a framework out this summer and begin consultation, and the goal is to have the regulations in place by early 2015. So that's a very tight time frame, the government of the day is pushing us very strongly to get this done as quickly as possible, so there's a lot of consultation going on and more to come. The highlights of what those new food regulations would contain would be a licensing regime for everybody involved in food, except those trading only within a province. So intra-provincial trade would not require a license, but everybody else who's exporting from province to province, to the United States, to Europe, would require a license and what would go with that license would be mandatory preventive controls. Now there are exceptions to this: We are not going to farmers and fishermen, it is not about primary producers, with the exception of produce, and it was very interesting to hear the discussion, we are watching very closely what's happening here in the U.S., and we will be having very much an enhanced produce inspection regime. Whether that involves mandatory licensing or not is yet to be seen, whether it involves mandatory preventive controls on farms for produce, a debate is taking place there, but we are watching what's happening here very, very closely. Obviously the industry in Canada is not nearly as large, but still, it is significant and it has implications for cross-border trade, as well.

So more effective inspection: I'm going to talk a little bit about the new inspection model, just that we're about ready to publish. We have a draft out there, we've had very intensive consultations over the past couple of years, and that will be published on our website, a final document of the new inspection model, which is really the vision of where we're going with this. We're going to be having better guidance documents, compliance promotion strategy, and there's a paper coming out on our website about how we will approach helping, really this is about helping small and medium-sized business dealing with these new requirements. Many of these regulated parties have never had to have a license; as a matter of fact, many of them have not seen a CFIA inspector for a number of years. So this is going to be a big shift, not without its challenges, but certainly well-supported from a policy standpoint and I think so far we've had very, very good support, although we'll see how it unfolds. We'll be moving to have the centers of expertise that I talked about across Canada in specific commodities, and investments in our laboratories.

Now I know you can't read this diagram. Some of you may have seen it before. What we tried to do is, our president of CFIA, George Da Pont, said, "Cam, you gotta figure out a way to do this on one page, in one picture." So this is our best effort at that. And I'm just going to focus on the center pentagon, which is really the five elements of our new food inspection model, and I'll – I know you can't read it, so I'll start by describing. On the upper right side, you'll see it says "CFIA Oversight." And this is significant because what we're saying is that we are going to be determining the risk, I know that's hard to define sometimes, the risk associated with any individual operation, and this way we can build a truly risk-based approach. This is one of the criticisms that we've received: Why do we spend so many resources on the meat inspection program versus the fish inspection program versus fruits and vegetables? So this system is led by our science group, and we are working very hard to have within the next few months a model out there that will describe how we will direct our inspection resources, the rigor and frequency of

oversight, based on the risk. And we will be looking at some of the work that FDA has done there as well. So this is very much different from what we've done in the past, and our resources have been allocated traditionally on just how, what resources were there when the programs were created, fifty, sixty years ago, and they sort of evolved individually, rather than as one common approach. The second piece, as you move around to the right and down is licensing, and this will, as I said, mandatory licensing for anyone in inter-provincial or export-import trade, and it will require, it's going to be a bit of an administrative challenge, certainly, but we won't be evaluating every preventive control before issuing a license; it will be an application, get your license and then inspect, but based on the risk associated with it inspectors will visit the facility, and obviously there'll be, higher-risk operations such as ready-to-eat meats and so on will be higher on that list. Of course, many of these plants are already registered or licensed under CFIA regime, and many of them have a continuous presence of veterinarians and inspectors already. It's really that group that have not previously been licensed with us, is going to be a challenge, for sure. Moving around, the next key element of the model is inspection, and what we're talking about here really is the inspector of the future. Moving away from that traditional approach, moving to a system where we are validating the controls and verifying that industry controls are working. I know this isn't a new concept in the HACCP world, but we have now a combination of very traditional approaches in some food programs, the sensory, kind of organic kind of approach, checking boxes and so on, moving very much to that audit systems kind of approach. And of course, this entails a significant culture change in our front line delivery. We have well over 3,000 front line inspectors and veterinarians, and many are already there, but there's also many of our staff who have been working in traditional programs and are going to have to change their approach in their way of thinking, so this is not a small challenge.

The next piece is moving around to compliance and enforcement, the fourth pillar of the new inspection model. This is really about just taking the same approach across all foods rather than that commodity-based, historical approach. And finally, the last key element and probably in many ways the most important, is systems performance. We've not done a good job in the past of really being able to get information out there that shows that our programs are delivering what they should deliver. And this involves surveillance and it involves data analysis, and so on. And this is important in telling our story to consumers, international trade, it's absolutely important that trading partners do not accept just, 'oh, we think we have a good food inspection program.' It doesn't work that way. We have to be able to demonstrate that our system is working. And also we are accountable to Parliament and the government, and we need better ways to demonstrate that public tax dollars are being well-spent. So I won't get into the rest of the diagram, I just wanted to touch on, those are the five elements of the model that are, I think, key to the future.

So I'm looking at the time and I'll be quick. The next piece is a commitment to service. I think I've covered this pretty well already. The changing culture, moving to service standards, an appeal and review mechanism, and investment in IMIT. We are investing in electronic certification so that industry can apply for an export certificate electronically, it can be issued electronically, and this is something that's long overdue and we received an investment in.

And the fourth pillar is a transparency agenda, and we've taken baby steps along this road with recall notices and so on, things like that. Ultimately, I can see in the next few year's where all reviews of food processing plants, potentially the corrective actions and those kinds of data will be available on the website. We have a major initiative on food labeling, which I really don't have time to get into, but we will be putting a food labeling tool up on our website. Labeling is, you'll hear more about that comprehensive food labeling review. And, so the results: It's a better, it's a focus on prevention, and it really is a new approach that we're taking. We really believe that it will result in a stronger food safety culture in Canada, and we really do appreciate the partnering that we've been able to do with the U.S. in this regard.

So just a couple of points on conclusion: We know that we have a strong food safety system, Canada. It's been demonstrated for many, many years, we always end up near the top in any rating and quite often tied with the United States. So it's a good system, but it has to evolve, and we have to build on it. And our emphasis is going to be on, as I've said repeatedly, preventing food safety risks, a more proactive preventive approach based on preventive control systems, HACCP, whatever you want to call it. It does mean that there will be new requirements for many stakeholders and that, as the discussions here, is always an interesting challenge, but so far it has gone extremely well.

And so we really I think have covered this already: We're going to have a stronger legal base, a safer food supply, we believe, a more consistent approach, and a new regime for licensing and preventive controls. So I rushed through that fairly quickly, I hope it was of interest to you, and thanks very much.

# The Impact of the Applied Science, Law, and Policy: Fellowship in Food Protection program for Food Regulators on Professional Development and Leadership Advancement

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## Abstract

The International Food Protection Training Institute Applied Science, Law, and Policy: Fellowship in Food Protection program was designed to provide experienced food regulatory professionals, from all areas of food protection, with critical thinking, problem-solving, and decision-making skills within the framework of food regulatory science, law, and policy. The potential impact of this ANSI-accredited program on the professional development and leadership advancement of the participants was investigated. Data was collected from program participants through open-ended survey questions given more than one year after completion of the Fellowship. Results indicate that the program is achieving its primary aim of increasing the leadership skills of the next generation of federal, state, local, tribal, and territorial food regulators, who are a critical component of our integrated food safety system that will protect the public from foodborne illness.

## Background

The field of food protection is evolving rapidly, and leaders in the field must manage change and growth. Through a multi-disciplinary curriculum team, The International Food Protection Training Institute (IFPTI) developed the first-ever National Curriculum for an integrated food safety system (Kaml, 2013). As part of the curriculum team work, an inventory of existing food protection courses was created. Over 700 existing courses were identified and classified into content areas within the National Curriculum, and gaps in current course offerings were identified. To fill one of the gaps in the National Curriculum, IFPTI developed the Applied Science, Law, and Policy: Fellowship in Food Protection (Fellowship), a national, standards-based training program accredited by ANSI and initially funded by the U.S. Food and Drug Administration (FDA).

The Fellowship, which is offered to future leaders from the federal, state, local, tribal, and territorial food protection community, comprises three week-long sessions over the course of one year and covers the following content areas: (1) Law, (2) Policies, Strategies, and Tools, (3) Labeling, (4) Evolving Science of Food Protection, (5) Food Systems Control Applications, and (6) Prevention, Intervention, and Response.



The Fellowship is conducted in an interdisciplinary environment, with experienced food regulators assigned as content-specific mentors and doctoral-trained researchers providing research consultation (Fogarty, 2011). Fellows complete a research project addressing a food science regulatory issue, present their results at the annual AFDO conference and their research is published in a special edition of the *Journal of the Association of Food and Drug Officials*.

The Fellowship focuses on competencies that future food protection leaders must achieve, including continuous learning, reasoning, decision-making, problem-solving, critical thinking, communication, self-management, interagency cooperation, and teamwork. These competencies were designed to represent the cognitive domain of Bloom's Taxonomy, which federal, state, local, tribal, and territorial government food protection professionals should possess after completing training (Huitt, 2010). According to AFDO Executive Director Joseph Corby (2011), *"Just as others have done, these new food safety leaders are destined to influence other individuals or groups to achieve common goals by applying the leadership skills and knowledge the leaders have developed. However, it will not be the authority they will have that makes them a leader; it will be their skill to influence others."* Corby further stated *"These new leaders will have such influence and will be great assets to their agencies and to the nation. We may all wish to design a new integrated food safety system in this country, but we most certainly will need these new leaders in our profession to help us influence others to build a new integrated food safety system and adopt it."*

The food regulatory officials selected for the Fellowship program were identified by their supervisors as persons destined to assume the role of national food safety leaders. These regulatory food safety professionals continuously develop their skills and capabilities, routinely take on important or complex assignments, and represent their agency in a personal and professional fashion.

### **Research Question**

What is the impact of the IFPTI Fellowship on the professional development and leadership advancement of participants more than one year after completion of the program.

### **Methodology**

Open-ended, online survey questions were developed and sent to the ten alumni (Cohort 1) who completed the Fellowship in 2010. This specific alumni cohort was selected due to the fact that they had the longest time since participating in the program and thereby had sufficient time to measure any reasonable short-term impacts. Seven of the ten alumni completed the survey, for a response rate of 70%.

The survey questions were designed to measure the professional impact of the IFPTI Fellowship on the participants' careers. Specifically, the alumni were asked to describe whether, since completion of the Fellowship, they had changed positions; had been given more responsibilities at work; had been more active in professional associations or work committees; had increased their leadership role in various capacities; had published a paper; or had presented at a conference or workshop.

Answers to the open-ended survey questions were analyzed as nominal data. Key word/phrase searches were conducted, and trends in responses were noted. No inferential statistics were attempted due to the nature of the data and the small sample size, which would have greatly limited the necessary power estimates and thereby the generalizability of the findings.

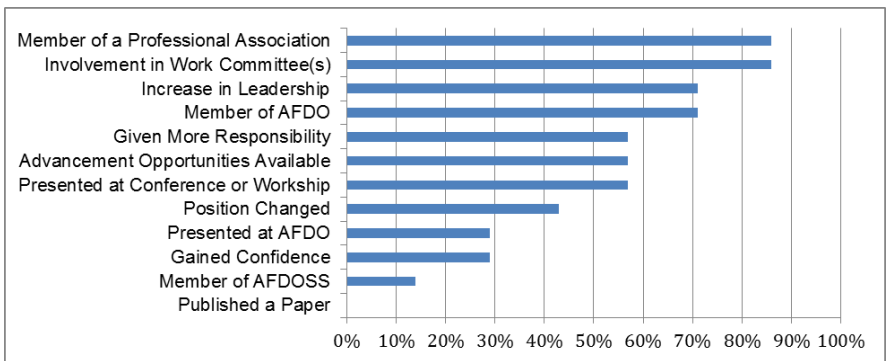
## Results

All but one of the 2010 alumni (86%) reported that they were both members of a professional association and involved in work committees since completing the Fellowship. AFDO was the most popular professional network, with 71% of the respondents being members (and 29% belonging to regional AFDO affiliates).

A significant majority (71%) of the alumni reported an increased leadership role since completing the Fellowship, while a majority of the respondents (57%) indicated they had been given more responsibility; had presented at a conference or workshop; and that advancement opportunities were available to them. Almost one-third of the respondents (29%) indicated that they had gained confidence since completing the Fellowship. Complete survey results can be seen in Figure 1 below.

None of the 2010 Fellows reported having published a paper; however, this question may have been misinterpreted, as all of the Fellows published their Fellowship projects in a special issue of the AFDO Journal. What is more, the question did not take into account that possibility that the respondents were, at the time of the survey, preparing a paper for publication.

FIGURE 1: Professional Impact of IFPTI Fellowship



## Conclusions

The data collected from this group indicates that more than one year after completion of the IFPTI Fellowship, participants increased their participation and leadership roles in professional associations and/or work-related committees. This finding is consistent with one of the primary aims of the program, which is to provide leadership skills to the next generation of local, county, and state food regulators. Participants have clearly

benefited from the Fellowship, and are starting to impact the integrated food safety system as emerging leaders in the food regulatory community. The IFPTI Fellowship is occurring at an essential time in our history, and addresses a critical gap in our ability to properly train a new cadre of engaged leaders. These leaders are necessary to help build a new integrated food safety system to protect the public from foodborne illnesses.

## **Recommendations**

The IFPTI Fellowship should be expanded to allow more food regulators to participate. This expansion should be a collaborative effort among IFPTI, FDA and AFDO leadership. Such collaboration will ensure that the components of the Fellowship address critical needs and provide leadership opportunities for the program alumni. The Fellowship could also be replicated internationally to develop a well-trained cadre of leaders in other countries, especially as our food supply is becoming more global in nature. IFPTI should also continue to survey Fellowship alumni on a yearly basis in order to substantiate or expand upon the findings presented here. Cohort 2 completed the program in 2011; Cohort 3 in 2012; and Cohort 4 will begin the Fellowship in 2013.

## **Limitations**

A limitation to the present research is the small sample size ( $N = 7$ ). However, the Fellowship welcomes just 10-12 participants a year. IFPTI plans on surveying Cohorts 2 and 3, which should increase the number of respondents significantly. Another limitation to this research concerns the misinterpretation of survey items due to the wording of the questions. To illustrate, one of the questions asked whether the alumni had “presented at a conference or workshop”. All of the 2010 Fellows presented original research at the 2010 AFDO Annual Meeting in Norfolk, VA, so 100% of the respondents should answer this question in the affirmative. However, 5 of the 7 alumni answered this item in the negative, which suggests that the wording of the survey question was misleading to some extent. As subsequent Fellowship alumni are surveyed, IFPTI will pay close attention to the wording of questions.

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## From the AFDO Archives (1940)

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### *False Advertising and the Consumer*

K.E. Miller, Senior Surgeon,

United States Public Health Service,

Medical Advisor to the Federal Trade Commission, Washington, D.C.

Presented at Association Conference, September 1939

*(reprint from AFDO Journal -- Volume IV, Issue No. 2, April 1940)*

I need hardly to explain to this audience the variance in the classification of food and drug work among the functions of State governments. It is rather my purpose to remind you of this fact and to emphasize this situation by citing statistical evidence. In a recent inquiry into the status of this work, it was ascertained that food and drug control is vested in the State health authority in only 19 states. In 18 states it is administered by the State Department of Agriculture; in 5 states this function is exercised jointly by the health and agricultural agencies; in 11 states by boards of pharmacy or other agencies; in 4 there is no agency specifically charged with this duty; and 2 states failed to submit any information on this subject. The first impression one gains from this state of affairs is that the health phases of this problem were inadequately understood and appreciated when certain of the State programs were inaugurated. This is undoubtedly true, and it may be added that this same lack of understanding prevails in large measure at this present time. This, however, is not strange in view of the ancestry of this class of work. While it may be true that some of the states undertook work of this kind before the Federal government came into the field, the Food and Drug Administration, which was set up in the Department of Agriculture by the law of 1906, not only furnished the impetus for food and drug control programs with the states, but in many instances also furnished the pattern on which the latter were constructed. It was thus more to be expected than otherwise that this work should have been made a function of the agricultural setup rather than becoming a part of the state health organization. It is not my purpose to argue the merits of either side of the case. There are instances under both arrangements where this work has been successfully administered. There are likewise instances under both arrangements wherein the results have not been impressive. But I believe there is an ever-growing conviction among all workers in this field that the most valuable contribution of this work to the public good is the health protection that is afforded thereby. In other words, the cardinal reason for the existence of this work is based on its value as a health measure. It is indeed deplorable that such an utter lack of uniformity exists among the states with respect to the management of food and drug work, as this necessarily handicaps any efforts toward a united front and concerted action. I can only express the wish in passing that this problem will be taken under serious consideration with the view to a more logical coordination of activities, not only between the several states but also between the states and the Federal government.

The State organizations which you represent are to a large extent miniature replicas of the Food and Drug Administration of the Department of Agriculture. It is therefore unnecessary for me to give any description of the functions of this latter organization. You are all familiar with the provisions of the law giving the Food and Drug

Administration jurisdiction over misbranding and adulteration and you are doubtless also familiar with the recently enacted Copeland Act, which materially extends, strengthens, and clarifies the basic laws under which the Food and Drug Administration previously operated. Within your respective State jurisdictions you, in turn, are responsible for exercising control over the same factors – misbranding and adulteration. But I would also call your attention to another potent factor in food and drug control which is probably little understood and appreciated by state forces concerned with this problem. I refer to the elimination of false and misleading advertising with respect to foods, drugs, cosmetics, and devices. It behooves you to study rather carefully this phase of the food and drug problem, since this is in a measure your own responsibility, just as are the duties connected with misbranding and adulteration. I shall therefore endeavor to explain something of the significance of advertising of this class of products to the health and welfare of the consuming public. In the further discussion of this subject, an effort will be made to establish a logical division of responsibility between the Federal and State governments. But first let me explain the background on which the participation of the Federal Trade Commission in this work is founded.

The Federal Trade Commission has, from its beginning 25 years ago, had for its primary function the elimination of unfair trade practices. The advertising of foods, drugs, cosmetics, and health devices constitutes a very large, if not the largest, portion of the advertising business. It therefore naturally falls within the province of the Federal Trade Commission to exercise jurisdiction over false advertising of this class of products, as well as others.

The original Act creating the Federal Trade Commission, being primarily designed to regulate unfair trade practices, required that a complaint against an advertiser should establish the fact that the interests of a competitor were being damaged, and that in the correction of such, unfair practice was secondary to the competitor interest. Moreover, this was not only a cumbersome method of handling false advertising, but one in which it was not always possible to establish jurisdiction, even in the face of glaring evils. Consequently an urgent need was felt for an extension of the law to facilitate action and otherwise to clear away the obstacles under which the Commission was laboring. This purpose was realized in 1938 in the passage of the Wheeler-Lea Amendment.

The more important provisions of this amendment are summarized as follows:

1. It declares advertising which may be false and misleading for any reason to be in violation of the law and defines false and misleading advertising in the following terms:

“The term ‘false advertisement’ means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.”

2. The consumer interest is emphasized by revision of Section 5, through the addition to the phrase "unfair methods of competition in commerce" the words, "or unfair or deceptive acts or practices in commerce." Thus the provisions to protect the consumer interest are not an innovation, but rather an emphasis of this purpose as set forth in the original act.
3. It provides special penalties for false advertising of any product.
4. It takes cognizance of advertising of products sold only to the medical profession, in the following language:

"No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug."

Before passing on from the discussion of legal authority and procedure, it should be pointed out that the Federal Trade Commission has no power to prohibit the sale of any product. It can only restrain the advertiser from making false, misleading, and fraudulent claims. Though a good proportion of difficulties are adjusted by voluntary agreement or stipulation, the Commission is empowered to issue orders demanding that the advertiser cease and desist from making false advertising representations. Should such orders be violated after becoming final, it then becomes the duty of the Department of Justice to institute appropriate prosecution, either civil or criminal, and to impose the prescribed penalties.

Whereas under the old law the origination of investigations was practically limited to complaints from competitors, under the law as amended, the Commission more often than otherwise institutes investigations on its own initiative. Since it is authorized to do so in any case where false and misleading advertising is suspected, it is obvious that the potential number of investigations is unlimited. Also the variety of problems involved in the study of advertising claims which relate to human therapy is unlimited. In approaching the appraisal of any set of advertising claims, however, two questions are uppermost: (1) Is the advertising in any way false or misleading? (2) Is the product likely to be harmful under conditions of usage which are customary or usual?

On either of the foregoing counts the consumer may suffer more or less serious damage. Assuming that a product may be harmless per se, but at the same time worthless in the sense that it fails to do what the advertiser claims it will do, it may be not only the means of depriving one of money which might have been used to purchase competent medical service, but also the means of precipitating untimely death. Every enlightened person knows the danger of delay in dealing with certain well-known killer diseases such as cancer or tuberculosis. In speaking of these and similar disorders, it is literally true that

"There is a tide in the affairs of men

Which, taken at the flood, leads on to fortune;

Omitted, all the voyage of their life

Is bound in shallows and in miseries”

Even more serious are those instances in which the product itself may be detrimental or dangerous. In those instances where the danger is grave or immediate, the Commission is authorized to invoke the injunction procedure. As an illustration of the class of preparations against which the Commission has already proceeded on the ground of harmful effects, the following excerpts from formal complaints of the Commission in application for temporary injunction are cited:

1. A fat-reducing remedy, containing dinitrocresol. Docket 3609.
2. An abortifacient remedy. The drugs contained in this preparation include ergotin, extract of cottonroot bark, extract black hellebore, aloes, oil of pennyroyal, oil of savin, and quinine sulphate, all of which are common ingredients of the abortifacient remedies. Other drugs contained in similar preparations against which the Commission has instituted injunction proceedings include ergot, apiol, and oil of tansy. Docket 2934.
3. A liquor habit cure, containing pilocarpine, emetine, and ephedrin. Docket 3735.

A question is often raised as to the meaning of the terms “deleterious” or “dangerous” in connection with drug preparations. In dealing with advertising I have found it necessary to adopt a viewpoint which may or may not coincide with your conception of these terms. Let us approach this subject from a common sense viewpoint. In a broad sense we must admit that all drugs having therapeutic effects have some degree of toxicity. Toxicity, therefore, is a relative term, depending largely upon conditions of usage such as the prescribed dosage, frequency of administration, the condition for which the drug is recommended, age, and the physical condition of the patient. Those drugs which, when used in the customary or usual dosage, involve a probable and likely hazard of physical harm must be regarded as deleterious. There are, however, certain drugs commonly regarded as poisons, which may be used in such a way as to be harmless. Even though this be true, drug manufacturers would probably be wise in excluding such drugs insofar as possible from their formulae, since it is now necessary to declare on the label the presence of poisonous drugs. Though a drug may be harmless under the conditions prescribed, the public, being unable to make this distinction, will tend to avoid any preparation containing a well-known poison. Also it is highly desirable to reduce to the very minimum the content of any drug which may be even questionable from the standpoint of acute or chronic poisoning.

It is the sole purpose of advertising to induce persons to buy. This is done not only by what advertising actually says about a product but also by what it implies. It makes a great deal of difference whether those who are induced to buy have a responsible prospect of securing the results promised them by the advertising. In the case of products intended for the treatment of disease and the restoration of health, a misplaced faith in their promised benefits may mean not only disappointment and

useless expenditure but may even result in loss of health and life. Consequently false and misleading advertising of medicinal and allied products is a serious menace to the health of the people. Let it be emphatically understood, however, that nothing which I shall say is in any way intended to be hostile to the right sort of advertising. On the contrary, legitimate advertising is a vitally important and useful factor in American industry and American welfare, and toward it the Federal Trade Commission has only the most benevolent and cooperative attitude. It is only the black sheep of the flock against which the hand of the law is raised.

Throughout the course of its existence the Federal Trade Commission has accomplished notable progress in the elimination of false advertising of food and drug products. As evidence of this, one needs only to turn to the files of newspapers and magazines of a quarter of a century ago and compare the advertising at that time with that of today. The older advertising was quite unrestrained and boldly exploited such claims as would stimulate a buying response, usually without regard to their deceptive character. The conservatism in advertising has a much more sustained pulling power than blatant falsehood. A few of the more commonly employed terms and practices in advertising of medicinal products will be cited as representative of questionable items:

In a survey of advertising representations, the term "cure" at once draws fire. In addition to the fact that rarely if ever is any drug preparation the medium through which complete recovery or cure is unflinchingly accomplished, the Commission has, rightly, I believe, taken the attitude that at best, drugs and devices can only assist Nature in effecting cures. Apparently advertisers are now pretty well aware of the hazards connected with the word "cure" in advertising copy. They often seek refuge, however, in such terms as "banishes," "ends," "does away with," "overcomes," "frees," "rids," etc. All these terms unfortunately are only poorly disguised synonyms of "cure" and are more or less subject to the same inhibitions as the word "cure" itself.

In my own estimation the word "relief" is the most used and most abused term employed in medical advertising. This is thought to be due to differences in understanding. For practical purposes I have adopted an interpretation with which you may or may not agree. If I have athlete's foot, for illustration, and buy a preparation which promises relief from athlete's foot, then by the use of such preparation I have a right to expect that I will cease to have athlete's foot. While this result would not be realized, it may nevertheless be entirely proper to promise temporary relief from the major symptoms of discomfort such as itching and irritation associated with that condition.

In other words, the term "relief" when applied to a disease condition is equivalent to "cure," whereas it may be properly used to indicate a palliative measure in connection with the symptoms of a disease or disorder. Even so, in most instances, it should be qualified by the term "temporary."

There is certainly no field of medicine in which there are so many "new discoveries" as there are among proprietary preparations. Since the public is always looking for something new, the so-called new discoveries for the treatment of their old ills should rate at least one trial each. At least I assume that this is the psychology back of the "new discovery" idea in advertising copy. Of course we all know that, with the rarest



exception, “new discoveries” are pure figments of the imagination, but how about the uninitiated public?

Three other closely allied words, “amazing,” “miraculous,” and “sensational,” are almost threadbare from excessive use. So much is this true that they have even lost some of their power to mislead, for the reason that the well-informed public has learned to discount such obviously inflated terms.

In the process of debunking, I hope that I may not be considered too iconoclastic. The advertiser is entitled and naturally expected to picture his product in its most attractive light. Even a few innocent superlatives may be condoned, provided the spirit of truthfulness is not violated. There should, however, be careful attention given to the proper limits of legitimate trade puffery.

One form of advertising is considered particularly difficult to use properly. I refer to the use of testimonials. Those who use this medium should do so with the full realization that they assume responsibility for any impressions created by statements of those quoted. If, for instance, an individual furnished a testimonial stating that he had rheumatism and was cured by taking a bottle of Dr. Bunkum’s Medicine, the advertiser is saying, in effect, to the wide world, that if you or I have rheumatism, we may expect the same result by taking the same medicine. It is gratifying to note that well-informed advertising specialists regard the testimonial type of advertising as being distinctly on the wane.

Almost too crude to mention is one of the oldest tricks in the advertising business, that of listing a host of symptoms, some of which we are all certain to have at some time, and any one of which may come from a great variety of different causes. By the power of suggestion, the individual is led to believe that dire consequences are impending unless he treats himself at once to a T. I. D. cocktail of Dr. Quack’s favorite remedy. Naturally this type of propaganda finds ready acceptance among neurotics, but unfortunately, it also swells the ranks of neurotics. While the modern advertiser is usually too clever to resort to such methods in their most flagrant form, this same theme runs through much of the advertising of the present day. More and more pictures and cartoons are playing a large part in advertising. Some of the most insidious and pernicious inferences are created in this way. Blatant misrepresentations may result from a series of pictures accompanied by the most innocent script, or even by none at all except the name of the product.

In order to impress upon you the fact that you are not dealing with trifles, may I remind you that the annual expenditure by the American public for health and beauty aids aggregates around \$1 billion. Taken as a whole, this represents one of the major industries of the United States. It would appear certain, therefore, that practically every American during the course of a year is affected either for good or ill by preparations of this nature. Unfortunately, the extent to which harmful effects are experienced is not reflected in the morbidity or mortality rates. As food and drug officials, it is your duty and mine to strip the advertising appeals of all sham and deception, so that the purchaser may be enabled to know with reasonable certainty what he will be able to achieve in the way of health and/or beauty improvement from any outlay he may make for preparations of this character. This brings us to a

consideration of what part of this undertaking is your job and what part, figuratively speaking, is mine. Since the great bulk of advertising is carried by the larger newspapers, magazines, and radio, it is self-evident that its distribution is essentially inter-state rather than intra-state. Consequently the first line of defense against objectionable advertising rests with the federal government, which can apply restrictive measures at the source and thus at the single stroke solve a given problem for each of the States at one and the same time. I would not, however, leave the impression that the states have no part to play in this program. There are, on the contrary, certain contributions which can be made only by the States. Some of these are outlined as follows:

1. Federal law extends only to products shipped inter-state. In every State there are perhaps drug and allied products which are made and sold wholly intra-state. State regulations should be such as to control this group of products. Moreover, there is nothing to hinder anyone who may have run afoul of the federal laws from setting up a series of separate merchandizing units in the several states and confining the business of each wholly within the borders of the State in which such unit is located.
2. Even among those drugs which are extensively sold inter-state, the federal laws are sometimes powerless to exercise control. A splendid example is sulphanilamide. It is understood that in 1938, over 180 tons of this drug were sold in America and that much of this went to the over-the-counter trade. The laws governing misbranding and adulteration are not violated in this way, and likewise the laws governing false advertising or the advertising of dangerous drugs do not apply, for the reason that no advertising at all is involved. Yet the fact remains that the distribution of sulphanilamide through unethical channels to the lay public constitutes one of the most serious menaces to public health at this time and is one which is growing daily more acute. The obvious demand is for local regulations to supplement the federal laws and for the vigilant policing of sales by State and local authorities.
3. With respect to laboratory analyses of drug samples, it is proposed that a reciprocal relationship between the State and Federal laboratories would be both practicable and helpful. For example, when an analysis is made by a federal laboratory, a copy of the findings could easily be furnished to any state health department desiring this information, and, vice versa, analyses made by the State laboratories might be furnished to a Federal laboratory with the understanding that they be redistributed to the other states.
4. Whenever trial on a complaint by the Federal Trade Commission is scheduled, it becomes necessary to secure competent medical testimony. The Federal Trade Commission must appeal to some agency within the State to assist in obtaining the services of suitable medical authorities. This function can be performed either by the State health agency or the State Medical Association. As a matter of fact, it has been performed by both with a degree of satisfaction. Since this phase of the proceedings is often the most essential link in the chain, it will be readily seen that in arranging for this service, a highly important contribution is made.

5. Not the least of the contributions that can be made by State and local authorities to the drug control program is through the educational approach. Complete effectiveness will never be accomplished by law enforcement alone. A law which commands more respect than all others is the law of diminished purchasing response, which becomes effective only insofar as the public is informed of evil consequences that may result from falsely advertised or harmful drug preparations. It is obviously the function of State and local authorities to interpret to the public the potentialities for harm that may emanate from falsely advertised drug preparations. For this purpose the systematic use of the routine educational facilities will suffice. If the people are made aware of the truth, they may be relied upon to do the rest. But to convey the truth to others, the responsible parties must first know the truth themselves. It is suggested that the most fruitful source of such information is found in the Federal Trade Commission. I have reason to believe that this organization would be happy to supply all interested health or similar agencies with copies of all stipulations and cease and desist orders which clearly define the grounds upon which official action is taken. Were the pertinent facts in this material to be relayed to the public and followed up by appropriate comment, an enlightened popular interest in these problems would be expeditiously achieved, and the law of diminishing buying response toward unworthy drug preparations would automatically become effective.

***Food Utensil Disinfection***  
**Walter W. Burdette, Assistant Director,**  
**Bureau of Food Inspection**  
**Health Department of District Columbia, Washington, D.C.**  
**Presented at Central Atlantic States Association, May 16, 1940**

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During the years 1936 and 1937, renewed interest was created in the destruction of disease-causing agents attached to the rim of drinking glasses in public eating establishments.

Likewise, in the year 1937, after a thorough investigation was made of the bacteriological content of drinking glasses in Washington, D.C., it was decided that a standard be set for this jurisdiction, requiring each glass unit served to the public to contain no more than 500 bacteria.

An educational campaign under the Direction of the Health Department, aided by the field bacteriologists, was inaugurated. The proprietors of the various eating establishments were called in for conferences on this subject and heartily joined forces with the District of Columbia Health Department.

Our investigation of the various facilities for disinfection of glasses indicated that proper bacteriological results could be obtained with the following equipment:

- Three compartment wash tanks, each having dimensions of 16 cubic inches
- Compartment one to contain water with a good soap or other detergent used for washing refuse from the used glasses
- Compartment two to contain clear water for finishing glasses removed from compartment one, water temperature to be about 120 degrees F
- Compartment three to contain clear water at a temperature of at least 170 degrees F, used for immersing glasses for a period of three minutes.

With the aforementioned equipment decided upon, the campaign was inaugurated in November of 1937, the month during which all food-serving establishments are required to renew their licenses for the coming year. It was therefore decided that before a license was approved for such an establishment, the above equipment would be required to be installed, and a bacteriological test made of the glasses must show a count of less than 500 per unit.

Four field bacteriologists were employed, whose duty it was to make systematic inspections of all public eating places in the District of Columbia. At the time of this inspection, a group of glasses, usually ten, were swabbed about the rims in order to ascertain the average count of each glass.

When a bacteria count was found in excess of the fixed standard, the proprietor of the food establishment was summoned to the central office of the Health Department, where weekly meetings were held with the offenders in order that their individual

problems might be fully discussed and information given to improve their methods, so that compliance with our bacterial standard would result.

In order that the observations might be obtained during all hours of operation, the investigations were not limited to the daytime alone. Each night an inspector was detailed to observe whether the vigilance of sterilization was relaxed and to make examinations of drinking glasses in order to encourage cooperation during the entire time the establishments were open.

In tabulating the results of these bacteriological examinations, it has been found that adequate facilities, while of great importance, are not the controlling factor. Method and the human element continue to be the basic factors which determine whether or not the job is properly done. In many instances, highly priced and well-equipped establishments have failed to secure desired results, while on the other hand, establishments using the usual facilities have consistently obtained splendid results. This is neither a condemnation of good equipment nor an approval of minimum facilities. It does serve to demonstrate, however, that facilities alone, if unaccompanied by personnel who are careful and observant of instructions, will avail little. Good equipment plus competent, intelligent personnel is the formula for proper results.

We have noted with the development of this campaign that the standard of bus boys and dishwashers has appreciably improved. Whereas formerly straggling, shifting, and uninterested transients were delegated this important task, today, employers are making an effort to supply themselves with intelligent help in their kitchens, help who understand and follow instructions.

In those instances which clearly indicated a failure to heed instruction, coupled with continuing high bacteria counts, the establishments were cited with warrants, and such cases were referred to Police Court. Approximately 58 cases were referred to the Office of the Corporation Counsel for prosecution during the year 1939, in which almost 100% convictions were obtained. In most instances, marked improvement was obtained by following this course, it appearing that only by such punitive measures can the attention of some lax and careless restaurateurs be aroused.

Although the Department recommends as preferable the methods of disinfection described at the outset of my remarks, the wash, rinse, and sterilize method has not been made exclusive. Those establishments which for their own reasons prefer chemical and chlorine sterilization are permitted to employ this method but are subject to achieving the results which are fixed by this Department. Chlorine sterilization is prevalent, however, in only a small percentage of our local establishments, and in some instances, satisfactory results are achieved. Due to the care which is required and the knowledge necessary for proper use of this means of disinfection, we feel that it is hardly advisable for the general employment of chemical sterilization. In the opinion of this office, the wash, rinse, and sterilize formula by the use of hot water still constitutes the safest and surest means of achieving the desired results.

It has been clearly revealed during the course of inspections and weekly hearings that in many instances the reason existing for failure to achieve desired results on the part of earnest and well-meaning operators is due to concentration on the question of

disinfection and abject disregard to the necessity for proper handling and storage following sterilization. This is a matter of prime importance, as all too often the benefits of proper disinfection are often undone by the careless handling and thoughtless storage of utensils under insanitary conditions. In order to combat this source of difficulty, operators are constantly cautioned and advised to extend the vigilance of sterilization until the moment the glass is served to the customer. Careful handling, drying without towels, and storage under sanitary conditions away from contaminating influences all have an important bearing on keeping a clean glass clean.

Through the period of this campaign the proprietors have learned to rely upon the accuracy of our statements, and our claims are more than established by the facts. The standard of 500 bacteria per unit for each utensil was set as the maximum count. At present, approximately 90% of the establishments inspected are complying with the fixed standard.

In 1937, 50% of the glasses inspected were below 500; in 1938, approximately 68% were complying, and in 1939, approximately 80% of the glasses tested were below 500. With regard to silverware, in 1937, approximately 72% were found to be below 500; in 1938, 85%, and in 1939, more than 93% were meeting our standards.

May I add further that from our experience, observation, and belief, the determining of the sanitation of eating utensils by a bacterial standard is no longer an experiment or a speculation.

# Issues and Concerns with Imported Foods



**June 2013**



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**2014 MFRP Alliance**

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**May 11 - 16, 2014**

Hershey, Pennsylvania

**AFDO 118<sup>th</sup> Annual Educational Conference**

*Hosted by* **WAFDO**

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