



Journal of the Association of Food and Drug Officials

Serving the regulatory community since January 1937

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From the Executive Director

A Community of Trust and Respect

For almost two decades, AFDO has promoted the concept of an integrated food safety system. It's in all of our speeches, projects, and intentions as we press ahead, realizing that changing cultures of government agencies is a very long process. Furthermore, we understand the importance of keeping all stakeholders well advised of what is happening during this very long process. AFDO's "Integration Forum" to be held next April in Baltimore prior to the Food Safety Summit is specifically intended for addressing this matter.

There are many efforts we actively promote and participate in—the Partnership for Food Protection (PFP), the International Food Protection Training Institute (IFPTI), our Cooperative Agreements with the Association of Public Health Laboratories (APHL), American Association of Feed Control Officials (AAFCO), the National Association of State Departments of Agriculture (NASDA) (our FDA grant-funding program for state and local food safety agencies), and all the Alliances that were developed to address the newly proposed FSMA rules. All of these and the many others we are involved in have one major underlying objective critical in building the integrated food safety system we envisioned long ago. That objective is to build a community of trust and respect among all the government regulatory players.

Trust will be the key to sustaining agency relationships, and it should not be built on promises or MOUs. Having faith in each other's capabilities will make work planning and strategic goal setting easy to do. Independent efforts during multi-state or global response will be a sign of failure.

Respect is all about attitude, and we continue to witness the attitudes of stakeholders, agencies, and individuals changing enough that we can begin to say the concept is working and AFDO was right all along.



Joseph Corby
AFDO Executive Director

2014-2015 AFDO Board of Directors

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2014-2015 AFDO Board-Appointed Advisors

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Cynthia Culmo, Abbott Laboratories

Sarah Geisert, General Mills, Inc.

Jerry Wojtala, International Food Protection Training Institute

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2014 AFDO Award Recipients

The **Elliot O. Grosvenor Food Safety Award** was presented to the **Florida Department of Business and Professional Regulation, Division of Hotel and Restaurants** for their successful implementation of a statewide foodborne illness investigation and annual reporting program. Since 1997, the number of foodborne illness outbreaks in Florida's restaurants decreased by 84 percent. Ms. Diann S. Worzalla, Director, 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, **Ronald S. Klein**, was honored for his outstanding service and devotion to the administration of food, drug and consumer protection laws of our country. Mr. Klein served as Acting Chief of the Alaska State Environmental Health Laboratory and as Program Manager of the Food Safety and Sanitation Program for the Alaska Department of Environmental Conservation.

The **Associate Member Award** was presented to **Nancy Singer**, founder of Compliance-Alliance LLC. She previously served as AdvaMed's Special Counsel for FDA compliance and enforcement matters and began her career as an attorney with the United States Department of Justice, where she did litigation for the Food and Drug Administration. 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.

The 2014 **Achievement Award** was presented to **Chris Wagner** and **LaCronda Wilson**, Food and Drug Lodging Surveyors with the Kansas Department of Agriculture, Division of Food Safety and Lodging. The Achievement Award is annually bestowed to individuals who have 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 serve 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:

Allison Jane Orr, Florida State University, B.S. in Dietetics

Genette Lynn Stump, Old Dominion University, B.S. in Environmental Health

Brittany Wells, Eastern Kentucky University, B.S. in Environmental Health

2014 AFDO Resolutions

RESOLUTION NUMBER 2014-01

Submitted by: AFDO Board of Directors

Date: June 21, 2014

Concerning: Operational Structure for FSMA Implementation

Whereas, AFDO believes a fully integrated national food safety system will be required in order to meet the mandates of the Food Safety Modernization Act (FSMA), and

Whereas, state food safety agencies will play a critical role in partnering with FDA to advance integration and assist FDA in meeting these FSMA mandates, and

Whereas, current efforts such as state representative involvement on FDA FSMA Implementation Teams and AFDO's Food Committee FSMA updates have provided important but limited FSMA implementation information to state officials, and

Whereas, AFDO believes a more formalized operational structure which includes officials from FDA, AFDO and other stakeholder organizations would be helpful in developing strategies for implementing FSMA and assisting in the identification of available human, financial, and organizational resources, and

Whereas, an operational structure could also assist in the development and review of guidance documents, inspection protocols and compliance policies, and

Whereas, an operational structure could also be beneficial in developing a formalized funding framework for conducting training, outreach, assessments, and inspections in support of new FSMA regulations by state food safety programs, therefore, be it

Resolved, that AFDO request FDA to support the formation of a formalized operational structure to provide assistance and guidance in the implementation of FSMA, and be it further

Resolved, FDA considers formalizing this operational structure through a formalized agreement or Memorandum of Understanding (MOU).

RESOLUTION NUMBER 2014-02

Submitted by: AFDO Board of Directors

Date: June 21, 2014

Concerning: FSMA Compliance and Enforcement

Whereas, The passage of the Food Safety Modernization Act (FSMA) has created historic changes in food safety law on a national scale by authorizing increased enforcement, creating more accountability for industry, and mandating enhance partnerships between FDA and the states, and

Whereas, AFDO strongly supports the development of a fully integrated national food safety system as envisioned by FSMA, and

Whereas, AFDO believes an integrated food safety system must include the integration of the institutional knowledge and innovative approaches of state agencies relative to compliance and enforcement activities, and

Whereas, AFDO believes a highly coordinated approach will be essential in establishing enforcement and compliance programs for achieving and maintaining high rates of industry compliance with new FSMA regulations, therefore, be it

Resolved, that AFDO request FDA to solicit and incorporate state agency input into the development of a coordinated compliance and enforcement strategy that confers the primary role for enforcement to state agencies with jurisdiction over manufactured foods, and be it further

Resolved that FDA work with AFDO to determine what effective compliance strategies are currently in place at the state level and consider using these for the enforcement of FSMA regulations.

RESOLUTION NUMBER 2014-03

Submitted by: MFRPA Board of Directors

Date: June 20, 2014

Concerning: AFDO Training Proposal (Manufactured Food Training for State Agencies)

Whereas, PFP's Food Protection Vision for National Integrated Food Safety Systems has established goals including: leveraging resources, talent, and subject matter expertise and enforcement tools to achieve the best public health outcomes; and ensuring that partner agencies have food safety/industry oversight programs that are comparable relative to public health outcomes through the implementation of agreed upon program standards, and

Whereas, the Manufactured Food Regulatory Program Alliance (MFRPA) was established through a U.S. Food and Drug Administration (FDA) Cooperative Agreement with the Association of Food & Drug Officials (AFDO) to provide a forum for state manufactured food inspection agencies to review and recommend changes to the Manufactured Food Regulatory Program Standards (MFRPS) and identify and resolve regulatory program issues to help states meet the standards, and

Whereas, MFRPA members have elected a Board of Directors to lead the Alliance and help in identifying strategies for aiding state agencies in meeting program standards, and

Whereas, the MFRPA Board of Directors has established a Training Advisory Council to review and discuss concerns and make recommendations related to the delivery of training and education programs for employees of State, local, territorial, and tribal food safety agencies, including scientific training, training to improve the skill of officers and employees authorized to conduct inspections under contract with FDA, and training to achieve advanced product or process specialization in such inspections, and

Whereas, state agencies that conduct manufactured food inspections and are enrolled in the MFRPS have expressed concerns over capacity to respond timely and in an agile way to continuously changing or unanticipated state training needs and the availability and timeliness of training and education programs currently offered only by FDA/DHRD and other entities to support public health efforts, and

Whereas, AFDO has proposed to FDA a training model (Manufactured Food Training for State Food Safety Agencies to Support their Compliance with the MFRPS in a Nationally-Integrated Food Safety System) that addresses identification of training needs and delivery of manufactured food training for state agencies and proposes a system to provide Train the Trainer courses and qualify instructors where possible, and

Whereas, the MFRPA Board of Directors fully supports the AFDO training model proposal and believes that, if FDA adopts this proposal, it will help to address the training concerns of state agencies performing manufactured food inspections and will support development of a national integrated training program and mutual recognition of regulatory food safety programs.

Therefore, be it resolved, that AFDO continue to collaborate with and encourage FDA to adopt the AFDO training proposal and provide funding to support states in the protection of public health.

RESOLUTION NUMBER 2014-04

Submitted by: AFDO Laboratory Managers Steering Committee

Date: June 21, 2014

Concerning: The Partnership for Food Protection, Laboratory Task Group, Food/Feed Testing Laboratories, Best Practices Manual (Draft)

Whereas, the AFDO Laboratories Managers Steering Committee was established through a U.S. Food and Drug Administration (FDA) Cooperative Agreement with the Association of Public Health Laboratories (APHL), Association of Food & Drug Officials (AFDO) and the Association of American Feed Control Officials (AAFCO), which is intended to promote Laboratory Accreditation to ISO 17025 Standards. The Laboratory Managers Steering Committee provides leadership for facilitating state food and feed laboratory accreditation and integration with state and federal food safety surveillance, compliance, and enforcement programs.

Whereas, The Partnership for Food Protection (PFP) was established by the FDA, as a group of officials representing federal, state, local, and tribal governments to build the foundation of the integrated food/feed safety system in the United States, and

Whereas, The PFP established the Laboratory Task Group (LTG), led by FDA and state laboratory professionals and comprised of members from multiple federal, state, and local agencies to document best practices and procedures for food/feed laboratories to support confidence in the integrity and scientific validity of laboratory analytical data and facilitate the acceptance of laboratory analytical data by regulatory agencies, and

Whereas, the LTG developed the Food/Feed Testing Laboratories, Best Practices Manual (Draft), published by the PFP in November 2013, which is a set of tools, definitions, and references, that laboratories can use to improve their operations, and

Whereas, LTG included members of the AFDO Laboratory Managers Steering Committee and Steering Committee has reviewed and endorsed the use of the manual by food/feed laboratories to support confidence in the integrity and scientific validity of laboratory analytical data and facilitate the acceptance of laboratory analytical data by regulatory agencies, therefore be it

Resolved, that the AFDO Laboratory Managers Steering Committee, recommends that AFDO endorse the use of the Best Practices Manual to support confidence in the integrity and scientific validity of laboratory analytical data and facilitate the acceptance of laboratory analytical data by regulatory agencies.

About the Authors

Stephen Baker has been the Vice-President, Operations, at the Canadian Food Inspection Agency (CFIA) since July 4, 2011. Over the past few years, Stephen has achieved significant changes in the Branch, becoming a key driving force in implementation of the Agency's transformational, Change Agenda.

He joined the CFIA on September 16, 2008, as Vice-President, Finance, Administration and Information Technology (FAIT) Branch, later renamed to Corporate Management Branch from the Translation Bureau where he was Vice President, Corporate Services.

Stephen has more than 35 years experience in a variety of operational settings including government and the private sector covering accounting and financial management, information technology, business administration and project management. He has held a number of senior level positions in Service Canada, Human Resources and Development Canada and the Treasury Board Secretariat.

Mr. Baker holds a Masters of Business Administration from the University of Ottawa and is a Certified Management Accountant (CMA).

Ward Chickoski, Regional Director General Health Canada, Prairie Region. Ward Chickoski was appointed Regional Director General, Prairie Region, with Health Canada in April 2012.

Prior to this Ward was Deputy Director General, with the Department of Justice in Ottawa and has held senior management positions with the Privy Council Office, the Canadian Food Inspection Agency, the Canada Border Services Agency and Human Resources Development Canada.

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.

Health Canada contributes to improving and maintaining the health of Canadians by effectively delivering a suite of regulatory programs and specialized health services.

Jerry Elliott, Director of the Compliance & Investigations Division (CID), Food Safety and Inspection Service, USDA, has over 25 years of experience with FSIS – a career that has included time with the Office of Field Operations as well as Director of the Import Inspection Division. As Director of CID he is responsible for managing the surveillance, investigation, and enforcement of regulated meat, poultry and processed egg products in-commerce; investigation of foodborne illness outbreaks; and response to natural disaster and intentional contamination events. Dr. Elliott is a graduate of Purdue University School of Veterinary Medicine.

Ellen Morrison is the Assistant Commissioner for Operations in the Office of Regulatory Affairs at the Food and Drug Administration (FDA) where she leads a team serving as the focal point for coordination and management of ORA's field activities, including the approval and issuance of assignments from headquarters and centers.

The Office of Operations provides direction to field scientific resources, field import operations, and serves as the contact point to the U.S. Customs Service and other federal agencies involved in import activities.

Ms. Morrison received her B.A. in Biology from Regis College and she completed graduate work in Environmental Health at New York University; is a graduate of programs in Crisis Management and National Preparedness Leadership Initiative from the John F. Kennedy School of Government at Harvard University and also attained a graduate certificate in Terrorism Studies from the University of St. Andrews in 2013.

Ms. Morrison has worked in three FDA Districts and spent two years in a joint assignment at the Center for Biologics Evaluation and Research. In 2002, FDA named Ms. Morrison the Director of Emergency Operations, Office of Crisis Management, where she directed and coordinated FDA's emergency preparedness and response activities with other federal, state, local, and international agencies. In 2003, she became the first Director of the newly established Office of Crisis Management, where she advanced the priorities of the Commissioner through development and management emergencies, crisis management, and security policies and programs for FDA. Ms. Morrison returned to the Office of Regulatory Affairs in 2012 as the Acting Assistant Commissioner for Operations and a year later was named Assistant Commissioner.

She has received numerous FDA awards and special citations for her public service. She embraces her role as a public servant and mentor to the next generation seeking to protect the public health.

Dave Read is the Assistant Director of the Dairy and Food Inspection Division at the Minnesota Department of Agriculture (MDA). He is responsible for directing the animal feed regulatory and inspection program and the food regulatory and inspection programs at the wholesale/manufacturing and retail level.

Dave is currently President of the Association of Food and Drug Officials (AFDO) and has been active on a number of the association's committees. He is an advisor to the Manufactured Food Regulatory Program (MFRP) Alliance Board of Directors. He is also a Co-Chair of the Partnership for Food Protection's (PFP) Training and Certification Workgroup and is a member of the International Food Protection Training Institute's (IFPTI) Advisory Council and Fellowship Advisory Board. Dave is active in the Conference for Food Protection (CFP) where he serves on a number of committees.

Howard Sklamberg is FDA's Deputy Commissioner for Global Regulatory Operations and Policy, the Directorate comprising the Office of Regulatory Affairs and the Office of International Programs. Mr. Sklamberg provides executive oversight, strategic leadership, and policy direction to FDA's domestic and international product quality and safety efforts, including global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities.

Prior to being named Deputy Commissioner in January 2014, Mr. Sklamberg served for one year as Director of the Office of Compliance at FDA's Center for Drug Evaluation and Research (CDER). He led the Office in its efforts to protect the American public from unsafe and ineffective drug products. Mr. Sklamberg played key leadership roles in global drug supply chain security, pharmacy compounding oversight, pharmaceutical quality, and expanded cooperation with international regulatory partners.

Mr. Sklamberg also served as FDA's Deputy Associate Commissioner for Regulatory Affairs in the Office of Regulatory Affairs (ORA) from July 2011 until he joined CDER in January 2013. Prior to that, he was Director of ORA's Office of Enforcement. Mr. Sklamberg's work in ORA led to the development and use of the Food Safety Modernization Act's new enforcement tools.

Before coming to FDA, Mr. Sklamberg was a federal prosecutor serving as deputy chief of the Fraud and Public Corruption Section in the United States Attorney's Office for the District of Columbia, as an Assistant U.S. Attorney in that office, and as a trial attorney in the Justice Department's Public Integrity Section. He specialized in the prosecution of white-collar crime. He is an adjunct professor at American University's Washington College of Law, where he teaches courses on congressional investigations and white-collar crime.

Mr. Sklamberg graduated from Harvard Law School, received a bachelor's degree in economics and political science from Yale University, and earned a master's degree from the Fletcher School of Law and Diplomacy.

Roberta Wagner was appointed CFSAN Deputy Director for Regulatory Affairs in July 2013. Ms. Wagner has worked for FDA for more than 28 years, 22 years in the Office of Regulatory Affairs (ORA) and almost seven years in CFSAN. Before re-joining CFSAN as the Director, Office of Compliance (OC) in February 2013, Ms. Wagner held the position of Assistant Commissioner for Operations in ORA for two years. In this capacity, she provided leadership to ORA's field force, principally investigators, compliance officers, and laboratory staff and the ORA headquarters components that supported/ interfaced with the field organization. Ms. Wagner began her FDA career in ORA's Baltimore District Office in 1987 where she worked for close to 20 years, first as an analytical chemist specializing in pesticide and industrial chemical analyses and applied research and then as a Supervisory Consumer Safety Officer in managerial positions in the District's Investigations and Compliance Branches including serving as the Director of each of these Branches. Ms. Wagner joined CFSAN the first time in 2006 as the Director, Division of Communication and Education; she served in this capacity for two years prior to assuming leadership positions in the Center's OC.

Ms. Wagner holds a B.S. in Biological Science with a minor in Environmental Science from Hiram College and a M.S. in Biochemistry from Bowling Green State University. Following graduate school, she was employed briefly at Johns Hopkins Hospital as a Research Assistant in the Oncology Department.

President's Address
David Read
AFDO 118th Annual Educational Conference
Denver, CO – Sunday, June 22, 2014

Welcome to the 118th Annual Association of Food and Drug Officials (AFDO) Conference. Our conference theme this year is: "Food, Feed, Drug & Device Safety – Mission Critical – Working Together"

Thank you for attending this year's conference.

What a year this has been. As I looked over the past few years Presidential remarks, Kilpatrick addresses, and keynote speeches the common theme has been integration and more recently the Food Safety Modernization Act (FSMA). Integration was the focus for the 1998 FDA/50 state meeting that was revisited and restarted at a FDA/50 state meeting in 2008, and emphasized in FSMA. The Partnership for Food Protection was born after the 2008 meeting to begin implementation of an integrated food safety system through the formation of a number of workgroups. FDA/50 State meetings have been held every two years since 2008 to report out on the progress of the workgroups projects and activities. The 2014 meeting will be in St Louis in August.

The amount of work to do to achieve full integration is overwhelming so the approach has been to identify priority projects and chip away at them. The funding needs to achieve integration are staggering so this will likely be a long term process.

I have a lot of people to thank for helping me and AFDO through the year. When I started as President about 30 pounds ago, I was a little apprehensive about being able to meet all of the commitments and being away from work so much. I've discovered that just when you think you finally understand and recognize the magnitude of the duties and tasks that need to be done, your term is up. As it turns out, there is never enough time to do all that needs to be done so I've left a mountain of unfinished and ongoing business for our incoming President Steve Stich to deal with. I couldn't think of a more appropriate place to do that than here in Denver in view of the Rockies.

How many AFDO Past Presidents do we have here today? Thank you for leading the way for me and the future AFDO Presidents. I'll soon be joining your ranks.

I'll start by thanking my wife Vicki for putting up with all the travel and time away from home. Although when I first started traveling to meetings she would say to me "you're leaving again" and soon that turned into "when are you leaving again." I think there may be a message there for me. She is here today in the back of the room. This is her first AFDO conference and my 14th. We will also be celebrating our 36th wedding anniversary on Tuesday although in different venues since she is going back to Minnesota tomorrow.

I especially want to thank the AFDO staff-Denise Rooney, Krystal Reed, Pat Smith and Randy Young for all of their help and hard work for the past year. They do a phenomenal job of running AFDO's affairs. What can I say about Joe Corby—the man's

an icon—he's a living legend. Thank you Joe for all of your advice and counsel. I also want to thank Ron Klein, Yvonne Salfinger, Jim Melvin, Art Johnstone and Mike Turner for their contributions to a successful year in managing AFDO's cooperative agreements with FDA. I will be talking a little more about that effort later.

How many of you have visited the AFDO website recently? If you haven't, please check it out at www.afdo.org. There is a tremendous amount of useful information from the Directory of State and Local Officials to program resources.

Thank you to the Local Arrangements Committee and Susan Parachini for their and her work on the ground here in Denver to make this all happen. Our conference hosts are WAFDO, the Rocky Mountain Regulatory Affairs Society (RMRAS), and FDA.

Thank you to all of the moderators and speakers on the program. It's a tribute to you as well that we have more than 400 attendees at the conference this year.

I'd also like to thank the AFDO Board for their advice and counsel and Barbara Cassens and Jeff Farrar for being available to discuss and work through issues as they arose. We held regularly scheduled conference calls and other calls over the year as needed to discuss current issues and activities.

I want to thank the Minnesota Department of Agriculture and Dr. Heidi Kassenborg for their and her support to allow me to spend the time on AFDO affairs and to the Dairy and Food Inspection Division staff who had to step in for me on numerous occasions while I was out of the office.

Attending the AFDO regional affiliate conferences was a high point of the year for me. For those of you who may not know, AFDO has 6 regional affiliates. AFDOSS (Association of Food and Drug Officials of the Southern States), CASA (Central Atlantic State 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).

I was able to attend them all except NEFDOA which fell into the same week as CASA this year. I'm hopeful for an opportunity to attend the NEFDOA conference in the future.

How many of you have attended affiliate conferences last year or this year? If you haven't you should check them out and join one or more of the affiliates and attend their annual conferences. Affiliate membership is a great opportunity to network with food and medical product professionals on a regional basis. There's a link to each affiliate's website on the AFDO web page.

I was also able to visit the AFDO headquarters in York, PA, or as some have referred to it as AFDO's World Headquarters. Again, it's amazing to see how a small staff of professionals can accomplish so much.

I can't stress enough the importance THAT you as AFDO members make AFDO what it is. It's your interest and commitment to food and medical products safety that makes this organization relevant and effective. Working together, we make a formidable team. It's

the people and relationships we build that make this organization work. It's an ongoing process because as people retire or leave the profession and new people arrive it takes commitment to maintain those relationships.

I would like to briefly report on some of AFDO's major activities and successes over the past year. Working on FSMA and implementing an IFSS have been a major focus. AFDO has prepared and submitted comments on 4 FSMA proposed regulations and will be submitting comments on two others soon. We didn't comment on the Preventive Controls for Animal Feed. Our comments are available in the dockets and on the AFDO webpage.

AFDO members have also been represented on the FDA's three FSMA Operational Teams. Ernie Julian from Rhode Island serves on the Preventive Control Team, Pat Kennelly from CA and Byron Beerbower from MI serve on the Produce Team, and Steve Stich from NY serves on the Import Team.

A major new initiative for AFDO in 2013 was the competitive grant application and the receipt of a Cooperative Agreement in September from FDA to design and implement a Retail Food Regulatory Program Standards (RFRPS) Funding System in Support of a National IFSS. FDA provided \$450,000 in funding for competitive grants to governmental retail food regulatory programs enrolled in the Retail Food Regulatory Program Standards (RFRPS). AFDO set up an easy to use web based application system that was operational by January 2014 and open for applicants in February. 311 applications requesting \$1.5 million were received. AFDO provided completed applications to FDA for review and selection of awardees. 155 awards were made for the \$450,000 available. FDA has increased the allotment to \$500,000 for 2015. If you are interested, the details about the grant program and the awards made are on AFDO's website. I would like to thank Cathy Hosman and Alan Tart from FDA for their assistance to Ron, Art, and Mike on the grant program.

The AFDO/FDA Cooperative Agreement called the Alliance for Advancing a National Integrated Food Safety System is in its third year of a five year project period. The Cooperative Agreement funds a number of activities to help states to achieve conformance with the Manufactured Food Regulatory Program Standards (MFRPS). One of the requirements for AFDO to deliver was to stand up a network of state manufactured food program managers called the Manufactured Food Regulatory Program Alliance. The Alliance has an operating Board of Directors and has established committees to review and recommend improvements to the MFRPS. The Alliance Board holds regular conference calls throughout the year and just met on Friday and Saturday here in Denver. The Alliance recently completed its third annual conference in March 2014.

A Food Protection Portal has been added to AFDO's website with extensive regulatory information and a topical index of laws and guidance.

Last year, AFDO conducted a FSMA related comprehensive survey of state and local jurisdictions to assess capacity, capability and responsibilities.

AFDO also is a partner with the Association of Public Health Laboratories and the American Association of Feed Control Officials in a Cooperative Agreement with FDA called "Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed." AFDO's primary responsibilities under this Cooperative Agreement are to build a community for food and feed lab directors, to assist them in advancing laboratory accreditation, and help state programs in meeting Standard #10 of the MFRPS concerning laboratory support for a regulatory food safety program. AFDO worked with IFPTI who developed a Laboratory Curriculum Framework as a blueprint for training food and feed laboratory professionals.

AFDO also developed a number of publications like the Imported Foods Guide, Meat & Poultry Processing, Safe Sausage Production, and A RETAIL FOOD ESTABLISHMENT GUIDE FOR DEVELOPING A HACCP PLAN. Check AFDO's publications site on the web for other available publications.

AFDO developed a short course for inspectors to help them improve documented observations and supporting evidence. The course will be piloted in Florida in July.

AFDO also had the cover story in the December/January issue of Food Safety Magazine titled "Association of Food and Drug Officials: Boots on the Ground for Food Safety." We have reprints of the article available at the conference and you can also find it on Food Safety Magazine's website.

AFDO members continue to actively participate in numerous outside associations such as:

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|---------------|---------------|---------------|
| ▪ AAFCO | ▪ PSA | ▪ US |
| ▪ FSPCA | ▪ CFP | ▪ Pharmacopia |
| ▪ OutbreakNet | ▪ NASDA | ▪ Convention |
| ▪ AOAC | ▪ SSA | ▪ CAP |
| ▪ IFT | ▪ Noro CORE | ▪ NERO |
| ▪ PFP | ▪ CIFOR(counc | ▪ USDA |
| ▪ APHL | il to improve | ▪ NACMPI |
| ▪ IFPTI | foodborne | ▪ FASGCC |
| ▪ PFSE | outbreak | |
| ▪ ASTHO | response) | |
| ▪ ISSC | ▪ NASMFID | |

At the 2013 Fall Board meeting last October, we met with the Grocery Manufacturers Association (GMA) and the Consumer Coalition to get to know each other better and to identify issues of mutual concern. We hope to continue meeting with these groups each year during the Fall Board meeting.

AFDO has been participating with NASDA to develop a proposed FSMA implementation plan for the Produce Safety Rules. The goal when completed and approved is to assist states that may choose to participate in the implementation of the produce rule when adopted. Areas of discussion include legal authorities, education and training, outreach, communication and information sharing, compliance and enforcement.

We have been meeting with FDA to discuss a number of AFDO initiatives to enhance training delivery capacity. More to come on those initiatives moving forward. Again, thank you for attending this year's conference.

Glenn W. Kilpatrick Address
Howard Sklamberg
Deputy Commissioner for Global Regulatory Operations and Policy
U.S. Food and Drug Administration
Glenn W. Kilpatrick Memorial Address
AFDO 118th Annual Educational Conference
Denver, CO – June 22, 2014

(transcript)

Good evening. I don't have any fancy geographical firsts about parts of a country. I was very impressed with the wonderful records that the Western Region has set.

It is a pleasure to be here. Thank you very much for the kind introduction and it's a true privilege for me to honor the late Glenn W. Kilpatrick. It's a pleasure, more importantly, to speak to the individuals keeping Mr. Kilpatrick's memory alive, not just through this address but through their hard exacting work each and every day.

It's all too common these days to hear a person referred to as a visionary. In fact, the word is often used to refer to someone perhaps earnest and sincere, whose ideas don't work now but might in the future or might not. However, we can say with authority and justifiable reverence that Glenn Kilpatrick was indeed a visionary. In fact, he passes the ultimate test for a visionary. Every day, tens of thousands of individuals across the country wake up and do the work that he set in motion more than four decades ago.

Mr. Kilpatrick saw the future that we as public health officials are living today. He established many of the cornerstones of the relationship between FDA and the states, the communications channels and joint planning. He went further. He knew that the federal government and the states should and could share responsibility in areas where authorities overlap. He significantly increased the commissioning of state officials so that they could continue to carry out activities on behalf of FDA.

He originated the program, still vibrant today, of FDA contracts with the states to carry out important inspections. While Mr. Kilpatrick foresaw a future of close and crucial federal and state collaboration, he and the rest of America when he joined FDA in 1970, lived in a smaller world.

By and large, the America back then and the FDA back then was a panorama within national borders. Today, that panorama has been enlarged by a new force. That force, massive and relentless is globalization. It is at the heart and even in the name of the organization I'm privileged to lead, which is the Office of Global Regulatory Operations and Policy, which consists of the Office of Regulatory Affairs and the Office of International Programs.

Each one of you in this room knows that the activities within our national borders already present huge challenges. Combined with this is a dramatically changing global marketplace. This change, in which the foods we eat and the medicines and medical

devices we use, increasingly emanates in whole or in part from countries other than our own. It has enormous ramifications for all of us.

And notice I say us because we are, of course, all in this together. In the foods area, U.S. firms are making business decisions to take raw materials grown or raised in United States and ship them overseas for processing. These products are then shipped back to the U.S. for either direct sale or further processing or packaging.

Another aspect of the challenge facing us is that global supply chains tend to be complex. For example, the production of a single commodity such as a can of tuna will involve the efforts of multiple parties from different geographic regions who fish, process, can, and distribute the product. The fish might be caught in the South Pacific and processed into frozen pieces. It may be transported to New Zealand for pre-canning or canning before being sent on to Southeast Asia for further canning or processing. Next, the cans may be shipped to one of our coasts and from there, distributed throughout the nation.

All of this volume, all this movement, all this complexity, all of it has huge implications for our ability to ensure that the safety and quality of products manufactured elsewhere is what we need and expect.

As for FDA, we have already begun to reorganize our structure and transform from a domestic agency to a global agency fully prepared for a complex regulatory environment that takes into account the risks across a product's life.

To give one example, we have greatly enhanced our ability to do targeted border screening, as products come in, using computer-driven, risk-based program, which we know as PREDICT. This system identifies imports that need fuller examination versus those commodities that are lower risk and thus can proceed through the domestic supply chain. But that, of course, is not enough. We know we have to enhance safety and quality of products long before they reach our shores, which is why we've enhanced overseas inspections and now have FDA offices in many parts of the world.

Again, we must do more. We simply cannot inspect our way to safety. Our task is nothing less than monumental, which is why federal-state partnership is absolutely critical. In reviewing the past Kilpatrick memorial addresses, it's gratifying to see the continuity of themes since the first address given in 1981, uniformity, communication, and cooperation.

As overwhelming globalization numbers demonstrate, federal-state partnerships are acutely needed today. AFDO has been absolutely critical in this regard. You've played an important role over the years by fostering national uniformity in food and medical product regulation and by fostering the integration of federal, state, and local food safety activities.

Indeed, FDA cooperation with the states continues the pace set with Mr. Kilpatrick's vision. State governments are performing surveillance, conducting inspections, testing products, and giving FDA feedback that is essential for ensuring the safety of products in the U.S. market.

Now, I won't claim to be a visionary. But I believe that someone giving the Glenn Kilpatrick's memorial address ten years from now would treat the notion of a bright line between federal inspection and enforcement action and a state enforcement action as the equivalent of us talking about dial-up access to the internet. It will be antiquated and obsolete.

There is another vital area which highlights our close cooperation, sparked by the meningitis outbreak of 2012, which is pharmacy compounding. From this tragedy has come clarifying legislation, the Drug Quality and Safety Act, yet another forum for FDA-state relations.

Indeed, just two months ago almost to this day, FDA held a useful and productive meeting with state regulators including representatives from the State Boards of Pharmacy and State Health Departments. Among the topics were the tools we already are using such as state license revocation and coordination on recalls and inspections.

All of us know that there is unique relationship between FDA and the states as regulatory partners in the oversight of pharmacy compounding. Remember my earlier comment. We're all in this together.

FDA has provided and is providing other opportunities for public input into its oversight of compounding pharmacies, such as publishing draft guidances and proposed rules for public comment.

We're also working on questions related to implementing the Drug Quality and Security Act in a public manner. And finally, we're working on a Memorandum of Understanding with the states on pharmacy compounding and hope to complete the process shortly.

Cooperation in the food area is particularly crucial this time since there has been a general recognition that the system for U.S. food safety needs to be strengthened. Federal-state integration is an essential component of a stronger national food safety system.

Furthermore, increased federal-state integration is required indeed as a prerequisite to the proper functioning of FSMA [Food Modernization and Safety Act] as part of the new regulatory landscape for foods. Food safety is a core public health issue and preventing food-borne illness will improve public health, reduce medical costs, and avoid the costly disruptions of the food system caused by illness outbreaks and large scale recalls.

In our increasingly interconnected world, we need a strategy that meets the public health demands of a global marketplace and addresses the complexities and challenges of food safety in the 21st century.

FDA also recognizes that FSMA will only be as useful as its on-the-ground implementation. Building a national integrated food safety system has long been a foundational element of our nation's strategy for carrying out an effective and efficient food safety program. It is a necessity. It is also one of the key themes of FSMA which calls for enhanced partnerships and integration with our federal state, local, tribal, and other partners.

We recognize that it will take time and a concerted community-wide effort for the wide range of farms to come in to full compliance with new requirements under FSMA. That's why FDA is committed to working with AFDO to facilitate compliance through educational and technical assistance and regulatory guidance. And when I say farms, of course I mean not just farms but all entities in the food safety system.

FSMA includes significant changes to FDA food safety authorities with the fundamental goal of asking importers and foreign food producers to take greater responsibility in protecting food before it is transported into this country.

Moreover, FSMA's new import authorities will enhance FDA's ability to help ensure the safety of imported food by building in new processes throughout the supply chain. These themes surrounding our approach to FSMA at their core are mutual reliance and efficiency.

I now want to take those themes to a more expansive horizon. I want to share with you an initiative that many of you know about that is important to me, to Commissioner Hamburg, to FDA, and that I believe to the entire regulatory community. And indeed to Americans as a whole in that it affects how we implement FSMA, how we ensure quality medical products, and how we really do our jobs.

It is called Program Alignment. It sounds a bit bureaucratic but I would like to explain the outlines of this initiative. We, FDA, are making fundamental changes in the way we operate. We're going to align our efforts across the agency to keep pace with scientific innovation and global market expansion.

As all of you know, so much of FDA's work and your work as well cuts across multiple product areas. That's why Commissioner Hamburg and senior FDA leaders are taking steps to achieve greater operational and program alignment across the Centers and our Office of Regulatory Affairs.

A key part of this effort is to enhance specialization across FDA. For example, for ORA, this means that investigators, compliance officers, import reviewers, laboratory personnel, managers and others will have increased technical expertise in specific commodity area and indeed, commodity sub-areas, and work closely with subject matter experts and the FDA Centers.

Over time, our field organization's geographic-based model will evolve to a commodity specific, program-based model that will provide our staff the opportunity to gain increased expertise in specific areas such as pharmaceuticals, food, animal feed, medical devices, biologics, and tobacco.

It's especially important that the experts in our Centers and in ORA be engaged in helping to develop compliance policies and priorities.

ORA and FDA Centers working together on these concerns will put investigators and compliance officers in a better position to direct the preventive approaches that are

required by the new legislation that has given FDA such important responsibilities both in food safety and in medical products.

I'll put it more simply. Clarifying the roles and responsibilities allows us to spend more time doing our job and do it more effectively and more efficiently and to better work with our federal, state, local, tribal, and regulatory partners. If we know our responsibilities and they're clarified and we have subject matter expertise and specialization, our job is not only more effective but will work better with all of you.

Now, the program alignment process still is in its early stages. There is a lot of planning still to be done and we're ensuring the process is transparent. And yes, I will tell you point blank, that changes like these are hard. If they weren't hard, of course, we would have done them a long time ago. But they're hard, and to me, they are absolutely essential for us in order that we perform our important work for the American public in the realms of food safety and for safe and effective quality medical products.

In my recent online travels, I checked in on the AFDO website. And yes, we receive your very informative online newsletters as well. And I was struck by this entry. "AFDO offers its members greater opportunities on a national scale, a voice on national regulatory issues, an opportunity to provide input international policy, and the opportunity to grow professionally with a regulatory leader."

This is maybe the most honest membership solicitation I've ever read. And it is a sentiment in keeping with your dedication to Mr. Kilpatrick some 34 years following his passing. Because this speech honors Mr. Kilpatrick, I want you, the audience, to consider a parallel in time.

Four months ago in a very routine fashion, FDA and AFDO teamed to launch the Retail Program Standards Grant Portal. In today's scheme of things, this is important but not surprising. Applications for grants are made available online, groups apply for funding online and for those fortunate winners, the funds are transferred electronically to the relevant bank account.

Visionary Kilpatrick more than four decades ago originated the idea of FDA funding state and other organizations. He did so with mimeograph machines and manila envelopes, rotary dial phones, and surface mail. Today, we do it all with a keyboard and a mouse.

As I noted, this portal demonstrates the timeliness of a fundamentally invaluable idea brought into the modern age. It's a great metaphor for our continued close partnership. Mr. Kilpatrick championed information sharing and leveraging of resources which has produced a true multiplier effect that helps us do our jobs.

Forty-four years ago after Mr. Kilpatrick's first days at FDA, we -- and now I mean all of us in this room plus the 313 million other Americans who count on us -- are all receiving a priceless return on investment in the form of safer and higher quality products. That's what I and what I know all of you would agree is the definition of a visionary.

Once again, I want to thank all of you for bestowing upon me the honor of delivering this memorial address. And I want, more importantly, to thank all of you for the job you

do for the American public. We are privileged to live in a country where people can eat food and use medical products without thinking first, "Is this safe?" And that to me is a testimony to really the work all of you do every day. Last, I would ask you, in those days when you have a difficult day at work, to take a step back and to think what you're actually doing and how important it is and how much it matters.

So with that, I want to thank you for the honor and privilege of speaking with you.

[Applause]

[End of transcript]

FDA Update
Roberta Wagner
Deputy Director for Regulatory Affairs
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
FDA – Progress, Trends, and Compliance

(transcript)

We are using analytics in the Center to better target what we are asking the field to do. As Ellen mentioned, our targeting must be risk-based as we only have a limited number of resources. So I'll talk to you about some of those initiatives and whole genome sequencing which is really going to be a game-changer in the food arena. So I thought I'd spend a little bit of time on that.

I present this slide whenever I speak now. I think people are very confused about how FDA has reorganized over the last couple of years. We do have a directorate structure now. I get questions often, "Do you have a Center Director anymore or is Mike Taylor running the foods program?" So I do like to show this slide which represents the Food and Feed Program in FDA and I emphasize the fact that this program actually spans two directorates and four centers and offices.

For the Foods and Feeds Program, we have a deputy commissioner for foods and veterinary medicine, Mike Taylor is. is the Deputy Commissioner for that directorate. In the Center for Food Safety, in the Center for Vet Medicine, those Center Directors, we do have center directors, report to Mike Taylor and then Mike Taylor reports in to the Commissioner whereas before, the Center Directors actually reported in to the Commissioner.

On the other side of the Foods and Feeds Program, we have the Directorate for Global Operations and Regulatory Policy. We call it GO. Howard Sklamberg, who spoke here earlier this week, is the Deputy Commissioner of that Directorate. He reports in to the Commissioner. He is equal to Mike Taylor. So you have Mike Taylor and Howard as Deputy Commissioners; the leadership and direction for the Foods and Feeds Program.

And then under Howard is the ACRA, Mel Plaisier. She is the head of the Office of Regulatory Affairs. And then we have an Associate Commissioner that's the head of the Office of International Programs. Again, the Foods and Feeds program spans two directorates and four Centers and Offices.

And what I want to mention is that as part of the Program Alignment initiative, and I would also say so that we can cope with FSMA implementation, we do have a cross organizational Governance Board for the Food and Feed Program now. It is co-chaired by Howard and Mike and then it includes the senior leaders in those four centers and offices, the Center Directors, the ACRA, et cetera, they are all on a Governance Board. This board which stood up a couple of months ago now is a decision-making body for

the Food and Feed Program. So we do expect to have one voice for the Food and Feed Program as we're moving along. And I think that's important.

I also get questions so I'll cover that here too. What's the difference between the Centers and ORA? And I put it at a very high level. In the Centers, you have subject matter experts, expert in very defined scientific disciplines. They serve as our expert witnesses when we take cases to court, a lot of PhDs, MDs. We set policy in the Centers. And when I say policy, and this is with input and in coordination with ORA, we don't sit over there by ourselves and develop policy. But it includes our inspectional strategies, our compliance strategies, our enforcement strategies, strategies developed at the Centers with input from ORA. And ORA executes the policy that is established in the Centers. So that's putting it at a very high level. That's the difference.

This is fresh from the graphics art department. It's our new depiction of FSMA implementation. We explained that FSMA implementation is definitely a continuum. As folks know, the law was enacted in January 2011, over three years ago now. It requires FDA to put out 50 rules, guidances, and reports to Congress. It's a massive effort.

And because of that, we are looking at implementation as a phased in approach. Phase one as I think Ellen mentioned is standard setting, the rule-making. It's really what we've been focused on over the past couple of years. We set up six core teams. Folks remember that really big diagram of how we set up a cross organizational structure with teams and workgroups with defined deliverables. That structure is still in place although a couple of the teams have finished their work and have been disbanded. But four of the teams remain active and they will remain until all the rule-making, guidance, and policy development are completed.

That's the middle tier of the triangle, setting the standards. We have now moved into what I call phase two, FSMA implementation. And that is, how are we going to implement these standards or how are we going to assure industry compliance with these new standards. We are now in what I call phase two. We are actually trying to get out of the FIT and FAT language. I will say our communications people in the foods program really don't like that branding. And so, we're now calling it phase one which is standard setting and phase two, FSMA implementation which is implementing those standards.

Relative to FSMA implementation of the standards, the second phase, we have set up a whole other structure. Ellen alluded to that. I'll show you a picture of it in a minute. Again, we have two structures going right now with cross organizational representation. Most of the teams in the workgroups are co-chaired by both an ORA person and a Center person so that we have the policy and the operation expertise together in driving how we're going to implement FSMA as we move forward.

Stakeholder engagement is around the entire triangle because this has been critical to first of all, making sure we get these rules right. We then have a very open process, a lot of public meetings. We believe that for phase two, implementing these rules, how we are going to have industry oversight gain industry compliance, it's just as important to have stakeholder input. You're going to see some public meetings relative to phase two here probably starting in the fall. We want input. We do have FSMA operations teams that have been brainstorming how we're going to implement these standards. They

have some very creative ideas. We really want stakeholder engagement around that. So it remains a priority. We need to get this right.

Phase one, principally has been focused on standard setting. What this slide shows is we had two core teams, the Preventive Controls Team and the Imports Team, collectively, they have put out seven proposed rules since 2011, which is just incredible, quite frankly. The second column on the slide is the dates that the proposals or the proposed rules were issued. I think most know that the FDA was sued by the Center for Food Safety. It was the Center for Food Safety versus the Commissioner. We basically are now under a court order to issue final rules in a certain amount of time and we were actually sued because they said we had not met the mandated timeframes in FSMA, in the law, for doing our rule-making.

The court order only covers these seven proposed rules. I've gotten questions around that. And again, our Commissioner will be in contempt of a court order if we don't meet these dates for publishing these final rules.

We have to publish the preventive controls for human food and animal food rules by August 2015. We have to publish the produce safety, foreign supplier verification program, third party accreditation rules by October 31st, 2015, sanitary transport final rule by March 31st, 2016 and then the intentional adulteration final rule by May 31st, 2016. In two years, we're going to have seven new final rules.

I should also mention that later this summer, and this has been alluded to in previous comments and presentations, we will be issuing re-proposals for four of these seven proposed rules. So the ones with the asterisk on the slide, we're not re-proposing the entire rules. We literally are re-proposing portions of the rules which we obviously did not get right based on the comments we received through the dockets.

To give you an idea of the number of comments we got through the dockets - and the majority of these were not in form letters this time - we got 30,000 comments between just the produce safety rule and the preventive controls rule for human foods. Going through these comments has been no easy task for the Agency. And again, we've drawn on ORA and CFSAN to help us get through these comments because we do want to review and touch every one of the comments. So re-proposals later this summer, again, please, please comment. We want to get these rules right.

We are now transitioning as I mentioned into phase two. We don't have the final rules but we can still do work to start framing out how we're going to implement these rules. And when I say implement these rules, what we want to do is gain widespread industry compliance through education, outreach, and technical assistance. And then we also have to develop longer term approaches for overseeing industry compliance with the rules. There are two parts here.

And what we've done like I said, we had six core teams. It's four now. They remain intact. They will remain in place until we get the rule-making done. And concurrently, we've set up another structure to start, again, framing out and developing implementation plans for the various rules.

And I'll show you a slide, as I think Ellen did mention, there are three work groups we have set up, imports, produce safety, and preventive controls. We're calling them the gold teams. Again, co-chaired by ORA and CFSAN or CVM. We have the policy, science and the operations folks together as we're moving forward on this next phase. And we have given a specific charge for developing a multi-year implementation plan that includes everything from education outreach, technical assistance to IT - how are we going to develop the IT, what are the IT needs - so we can implement efficiently and effectively. And obviously, we need to develop our inspection compliance and enforcement strategies.

That's the structure simplified. We have a steering committee. It is co-chaired by myself and Joann Givens from ORA. She is the Acting Regional Food and Drug Director for the Central Region. On that Steering Committee, we also have the Directors of the Offices of Compliance, from CFSAN and CVM. And we are attempting to get the Director of the Office of Enforcement and Import Operations from ORA, so again, our senior operations or compliance folks from across the FDA organization. The Steering Committee co-chairs, Joann and myself, are responsible for giving direction and guidance and support to the three workgroups. We report up to and sit on the Governance Board for the Food and Feed Program that I just described. We are in listening mode there, but we do attend the Governance Board meetings.

I should mention that for sanitary transportation and intentional adulteration, we actually have the subject matter experts for the rules, those involved in the rule-making sitting on the three groups, at least listening into their phone calls so they're being integrated in that way. And I should point out that there are states, at least one state representative on each of these workgroups. Produce actually has three state representatives. So we've embedded the states into our process for this next phase of FSMA implementation.

Transparency and stakeholder engagement remained a priority. If we want to get this right, we know we have to engage both our internal and external stakeholders. Relative to external, I mentioned we likely will be having public meetings come this fall around phase two FSMA implementation. Internally, Joann and I are going out to the district offices and having some two-way conversations with those that will be doing foods work talking about the operational strategy, what are the concerns out there. While we're out there, we do plan on meeting with some of the state regulatory partners as well. More to come on this, we really want Mel to get through her round of visits and then Joann and I will likely be going out shortly thereafter.

I should also mention, internally, we have what we're calling FSMA chats. This is a way that we're updating all our compliance and food safety staff in both the Centers and ORA. These chats are webinars. We've really been focusing these chats on the compliance staff in the Centers. In ORA, they're very well-attended, 500 or 600 people call in. So this is one way we're trying to keep people up to date with what's going on relative to FSMA implementation.

Compliance and enforcement, I'll shift gears here a bit. These are FY 2013 statistics. In FDA, we have three types of enforcement tools. I put them into three categories. We have advisory, administrative, and judicial tools. This slide is just CFSAN human foods

related statistics. And that does include dietary supplements. So I'll just throw that out there.

Advisory actions include our warning letters and we also, in some programs, have untitled letters. In an FY 2013, we issued 276 CFSAN related warning letters. Administrative actions now include detentions, mandatory recalls, suspension of facility registrations. FSMA gave us some of these new tools or enhanced them. In FY2013, we used our administrative detention authority six times and we also used our new mandatory recall and suspension of registration authority one time each.

Judicial actions include seizures, injunctions, and prosecutions. And just let me mention and expand a little bit on prosecutions. Know that criminal prosecutions are carried out by a distinct and separate group in the FDA. It actually falls under ORA. It's our Office of Criminal Investigations, OCI. These are gun carrying agents. They are disbursed across the country. They get their authority from Title 18 of the Code of Federal Regulations. They are separate and distinct from FDA field investigators.

And I want to emphasize that sometimes you're going to have an OCI investigation going on concurrently with what we do on the civil side. FDA field investigators get their authority to conduct inspections and investigations under the Food, Drug and Cosmetic Act and they are enforcing regulations in Title 21 CFR. That's the difference between our criminal and civil investigators in FDA; I get a lot of questions about that particularly since we've been doing some prosecution work in the foods arena lately.

Relative to judicial actions in FY 2013, we had 5 seizures, 11 injunctions, and 2 prosecutions. One of the prosecutions was felony and one was misdemeanor. I will talk to you a little bit about that in a minute. And whenever I present this slide, I do a lot of presentations to industry now in my current position, I emphasize the fact that these are the statistics for FY 2013. And we conducted over 9,000 food facility inspections. So, if folks think we're a heavy-handed enforcement agency, just please take a look at these statistics here.

And I would also say, people ask, "Well, why is that?" And this is my opinion, in most cases, when our investigators issue FDA 483s which by the way are their observations during an inspection, they typically can get the firm to perform voluntarily corrections. Sometimes we have to move to an advisory action such as a warning letter where we actually are citing very specific areas of non-compliance with the regulations. And again, after that warning letter, typically, we can get voluntary industry compliance. So there really is often not a need for us to move on and use our administrative and judicial tools. So I just want to put that out there.

This slide very quickly, these are the FY 2013 FDA enforcement statistics for all Centers - for drugs, devices, medical products, foods, feeds, etc. And the only thing I want to point out is that 5 of the 6 seizures were in the human foods arena and 11 of the 19 injunctions were in the food arena. Again, do note that food includes dietary supplements and we've been fairly active on the judicial side in that particular arena. In the recent past, folks have likely noted the agency has used criminal prosecution authority particularly in the foods arena against responsible firms and individuals that have been associated with foodborne outbreaks and illness. And more specifically, I

think you've seen this in the press, our DOJ has executed a felony prosecution against the responsible parties of the Peanut Corporation of America and misdemeanor prosecutions against the corporate heads or leads for Jensen Farms and Quality Egg, LLC. And Quality Egg, LLC was doing business as at Wright County Egg. That name may sound more familiar and Hillandale Farms, where we had a huge SE outbreak.

I'd like to emphasize that for misdemeanor prosecutions, the agency does not have to have proof that a defendant had knowledge of or participated in a violation. For felony prosecutions, on the other hand, we must show intent to violate the act or to defraud or mislead. We do believe in the agency that prosecutions can have a strong deterrent effect not only on the defendants but certain sectors of the food industry.

Jensen Farms was a misdemeanor prosecution. It honestly is the first time we've done a misdemeanor prosecution in the food arena in over 20 years, believe it or not. It followed a L. mono outbreak, one of the most deadly L. mono outbreaks in the US, 33 deaths. And the owners were charged, in part, with introducing adulterated food into interstate commerce. And then you can see what they got for that.

The two owners of Quality Egg, linked to the largest SE, Salmonella enteritidis, outbreak in U.S. history. In 2010, there was a recall of more than 550 million eggs. And they did plead guilty for, among other things, one count of introducing a misbranded food into interstate commerce, and the list goes on. They paid a \$6.8 million fine. This again is the most recently announced misdemeanor prosecution in the foods arena.

One related press release stated and I like this quote, "This is FDA's way of serving notice to the food industry that its leaders can be held criminally responsible for the products they sell." So this is intuitive. FDA may use a combination of its enforcement tools in response to foodborne outbreaks that caused human illness, hospitalizations, and death.

When we're in response mode, our first goal is to prevent further illnesses and we can do that by making sure that product that is still on the market gets off the market very quickly and making sure that implicated product that is still in distribution channels does not get distributed. Usually firms will do that voluntarily. But honestly, when they won't and we're in response mode, we will use our administrative and judicial tools. And in addition, it's not either or, we may pursue prosecution too.

Recall very quickly. There were 589 human food related recall events representing 2,039 recalled food products in FY 2013. A thousand of those, or 49% represent class one, 895 products or 44% represent class two, and the rest were class three. Mostly class one and class two recalls.

And pathogens specifically Salmonella, L. mono, and undeclared allergens continue to account for the majority of the food related class one recalls.

We did put out the Fourth Annual Reportable Food Registry Report very recently. It's data that is from September of 2012 through 2013, and there were some major trends that we saw there, primary entries decreased, undeclared allergen reports increased, produce related reports decreased both in raw agriculture commodities and the fresh cut, animal food and feed reports went up. Those are the general trends.

And this is no surprise. The RFR, Reportable Food Registry, pie chart mirrors that of the class one recall pie chart. There were 224 primary reportable food reports between September 2012 and 2013. The majority of these were due to Salmonella, L. mono, and undeclared allergens.

I think I have all of three minutes to get through 5 to 10 slides. So let me see what I can touch on very quickly. Again, the Center for Food Safety and ORA, we have a lot of very rich data. We traditionally haven't had the resources to look at that data in any systematic way. We are staffing up so that we can do that. We've created a whole new branch in the Center for Food Safety and Applied Nutrition to do data analytics work.

Some of what we've done in the very recent past is we looked at five years' worth of environmental sampling data, for example. We identified firms that had multiple inspections during that time period and that had multiple pathogen positive environmental samples in zones 1 and 2. We created a list of these firms and the field is out doing comprehensive inspections including environmental sampling at these firms, just one way of better targeting our field resources.

In addition, the Center for Food Safety created what we call our chronic bad actors list. We looked at 5 to 10 years' worth of data. These are the people that are never NAI, just can't get it right, always VAI or OAI. Some of them are under consent decree and they still can't get it right.

So this particular list, and we had to overlay a lot of different data streams and just like everybody else out there, I'm sure you're data streams are not interoperable. So this is a very manual process for FDA right now. We looked at everything from the inspection data and the compliance data of course but also RFRs, recalls, consumer complaints, we looked at Dunn and Bradstreet financial viability data. We overlaid all of this data to come up with this chronic bad actors list. And all I'll say is this group of firms will be under intensified scrutiny by the agency for a while.

Folks mentioned our new microbiological surveillance sampling program. We are piloting this right now. CFSAN and ORA created the pilot, the new model. What we're piloting is whole pit avocados, sprouts, and aged cheese. What we have traditionally done in the FDA or on the food side is we cast a wide net. We collect a small number of a lot of different commodities in the micro arena and test them. And because we've done that, we have not collected enough data to actually use in our decision making and policy development.

In summary, what this model does is a) focus on the highest risk commodity pathogen pairs. We worked with our statisticians in the Center to develop sampling schemes that allow us to answer specific questions or fill specific data gaps. We will be collecting larger numbers of less commodities over a short period of time, about 12 months. And we are going to be looking at this data real time. It's an iterative process.

For example, if we look at whole pit avocados for salmonella, we don't have prevalence data for salmonella in avocados right now, the whole fruit, and we see that we got absolutely no positives after we collected 1,600 samples which would allow us to detect about a 1% prevalence rate, we may choose not to sample a lot of whole avocados for

salmonella in the future. This is how the model works. Collecting data to fill data gaps, answer questions, and then based on the results, which will be reviewed in real time, not ten years later, we will make decisions on how we're going to allocate resources in out years. I'll skip through the rest of those.

People ask me a lot, "How did you come up with those three commodities for the pilot?" We did have a risk prioritization process that occurred before we even started the pilot. We ended up with 200 commodity pathogen pairs. The criteria we used for prioritizing these pairs are on the slides so you'll have them in your slide deck. . From the 200, we identified the 20 top commodity pathogen pairs, identified based on where we have signals that there could be emerging problems or where we have a data gap. Perhaps, we are thinking about changing a regulation or want to relook at a policy. These were some of reasons for the pairs to end up in the top 20. The three commodities were picked because we wanted to pilot this new model and we wanted a very diverse set of commodities and circumstances to pilot.

We wanted to include in the pilot where we had to collect both imported and domestic products, where we had to use our Food Emergency Response Network (FERN because we didn't have enough resources to test using only our FDA labs. We wanted to include environmental sampling and product sampling. That's why we included these three particular commodities.

These are the pathogens that are covered under the microbiological surveillance program, the new one. Regarding whole genome sequencing, very quickly and I'll probably just go over this slide. I want folks to know what's going on in the agency relative to this. FDA Center for Food Safety has actually taken the leadership role in establishing the use of this new technology in the public health and regulatory foods arena.

The fact is that you now have sequencers that cost very little money and the cost for the whole genome sequencing reaction is no longer cost prohibitive. So basically, you now have a technology where it's very cost-effective to do this. You can do it very quickly. In fact, we can do the whole genome sequencing of a pathogen as quickly as we can do PFGE at about the same cost.

It's fast-becoming an integral part of the food safety regulatory arena. We used it to support a regulatory action a few weeks ago. So this is technology of the future and we are working with our legal staff to figure out how we use it to support regulatory actions now.

CFSAN has created and we're piloting the first integrated network of state, federal, and international public health and regulatory labs to use whole genome sequencing principally for tracking foodborne pathogens and improving outbreak response. Right now, this network that we have set up, we call it Gene Tracker. It is operating akin to Pulse Net. So just think about it, we are creating a Pulse Net like integrated system but with whole genome sequencing.

Again, the network is called as the slide indicates genome tracker. Genome tracker is a publicly available global database; it contains the genetic makeup of thousands of foodborne causing bacteria. Salmonella, L. mono and the STECs are the focus right now.

Our pilot currently consists of 11 FDA field labs, 7 state laboratories, and I should mention that 12 state laboratories now have the technology. In addition, CDC is using FDA's genome tracker network to enhance its real time surveillance for L. mono. In fact, all isolates for L. mono right now, clinical, food and environmental are going into gene tracker. And we are making some very interesting connections. As you're aware with L. mono, we get a lot of sporadic cases and CDC has a hard time attributing them to a food. I think whole genome sequencing is going to help us in this arena.

The goal is to further enhance the network by growing the database and adding partners from public health and regulatory agencies around the world. And as the slide depicts, we are already getting isolates and or sequences from places like Mexico, Argentina, England, Ireland, Denmark, and Canada. We have gotten isolates from Colombia, Turkey, Chile, and China. What whole genome sequencing is going to allow us to do, in short, is source track. We will be able to get to the source of the contamination far more quickly or pathogen contamination far more quickly than we could before.

I'll leave you with that. Again, whole genome sequencing is the wave of the future. And we are setting up the infrastructure now to have the clinicals, environmentals, and food samples all in one place; we'll be able to use them hopefully to prevent foodborne illness.

[Applause]

[End of transcript]

Health Canada Update
Ward Chickoski
Regional Director General
Health Canada - Prairie Region
Health Canada – Progress, Trends, and Compliance

(transcript)

I'm pleased to have the opportunity to once again be at AFDO. Along with some of you, I had the opportunity to be in Louisville Kentucky last year. And on behalf of Health Canada, we're very pleased to be back again this year to give you an update on some of the activities, priorities and initiatives that we're advancing.

My name is Ward Chickoski and I'm the Regional Director General for Health Canada's programs in the prairie provinces of Alberta, Saskatchewan, and Manitoba. We also provide service delivery to our three Northern territories.

For us, participating in AFDO is a critical component of reaching out and building partnerships. And so, I know over the last couple of days, the opportunity to share our collected collective experiences, to share best practices and to be able to come together to enhance those partnerships, for us is a critical component on our international initiatives.

I'd like to just take a moment because this year, we have a number of colleagues who are representing Health Canada. And so, I'd like to just take a moment to introduce them to you and hopefully over the next day or so, if you've got questions or comments, I'd be more than happy to connect with you myself. But these individuals are also the ones on the ground delivering our programs.

And so, for the first individual, I don't think he needs much of an introduction., He has been an active member of the AFDO community for many years, has been Health Canada's point person, and has also been the chair of the international and government relations committee, so Bob Scales, if you could just stand up for a moment.

[Applause]

Also, our Compliance and Enforcement Lead out of Quebec Region, Peggy Farnsworth.

[Applause]

And also, from our Prairie Region and part of our Compliance and Enforcement Management Team on the Inspectorate, Alexis Grolla.

[Applause]

So, I'd like to take the next couple of minutes to give you an update on some of the priorities and initiatives on the behalf of Health Canada. And I guess as far as positioning Health Canada, the organization and what it might mean to you in relativity to the FDA

and other organizations, I'd like to just take a minute or two to give you a brief overview of our mandate and our structure.

Overall, Health Canada has a very broad mandate. In addition to food and drugs, we're 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 we also provide health services to our First Nations on reserves as well as our Inuit people in the North. We also work with the provinces and territories to ensure that our healthcare system serves the needs of Canadians nationally.

Flipping to the next slide with regard to our structure, in Health Canada, the regions are primary delivery mechanisms across Canada. Over the last couple of years, we've streamlined our program and operational delivery. And it's modeled around three clusters. So the first cluster is Health Programs, which is predominantly composed of environmental health programs connected to the health elements on environmental assessments, contaminated sites, air quality, radon, as well as the Chemical Management Plan.

Also, linked to this is the laboratories component. So we have forensic drug analysis labs across the country, food labs, as well as a food policy component that we tap into quite regularly.

An example of some of the food policy work we do in the regions is the guidance we provide to industry and trade associations throughout their product development processes on regulatory requirements for food with health claims. For example, we're currently collaborating with Pulse Canada to promote awareness about the health benefits of pulses. These are the edible dried seeds of plants in advance of the 2016 International Year of Pulses.

The compliance and enforcement component of Health Canada's mandate covers a number of regulatory program streams. Some of these include the Product Safety Program, Tobacco Control, Pesticide Compliance, and Controlled Substances.

Another example of some of the compliance and enforcement work we do in the regions includes engagement with health professionals to promote adverse reaction reporting which enables Health Canada to monitor the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks.

Given our mandate and our commitment to help Canadians maintain and improve their health, one of our priorities that we continue to advance is in the area of Natural Health Products.

The term Natural Health Product is 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, homeopathic medicines, fatty acids, probiotics, and some personal health care products. These are better known in the United States as dietary supplements.

Natural Health Products are regulated in Canada under their own specific regulations which take into account the unique nature and properties of these products. As part of our ongoing commitment to continuous improvement, the government of Canada has developed a new approach to these products. After consulting with stakeholders, consumers and political representatives, we've identified a need for increased access to products while maintaining consumer safety and also reducing the unnecessary administrative burdens for companies that are trying to bring safe products to market.

In 2012, the new approach was implemented that provides a more efficient, flexible regulatory process protecting the health and safety while enabling consumer access, industry innovation, and growth. Under the new approach to Natural Health Products, application review times are based on how much is known about a particular product and its risks and benefits, relying on the information that's amassed from over 70,000 authorized Natural Health Products. This means that the products with the greatest level of certainty are subject to the shortest review times.

With respect to compliance and enforcement of Natural Health Product regulations, Health Canada is continuing an emphasis on compliance promotion. Once the transition period ends in September, products without a product license will not be available – for sale or import in Canada.

With respect to food, we share the responsibility for food policy and programs with other federal departments in Canada along with our provincial and municipal governments.

When it comes to food labeling, Health Canada and the Canadian Food Inspection Agency, who you will hear from later this morning, play joint roles. Health Canada establishes the policies, sets the standards, and provides advice and information on the safety and nutritional value of food while the Canadian Food Inspection Agency provides all federal inspection services related to food and enforces the food safety and nutritional quality standards by Health Canada.

We support the CFIA by performing health risk assessments and collaborating on research and the detection methods for priority threats to the food supply. In October of last year, the CFIA joined Health Canada as well as the Public Health Agency of Canada in reporting to our Minister of Health. It's felt that this reorganization will strengthen Canada's food safety system by bringing all three authorities responsible for food safety under one minister.

One of Health Canada's big priorities at the moment in the food policy areas includes food labeling. Recent events of food-borne illness derived from mechanically tenderized beef have underscored the need for consistent and enhanced food labeling to provide better information to consumers.

In May of 2014, Health Canada published regulations amending the food and drugs regulations on mechanically tenderized beef to enhance labeling of packaged product. The new regulations introduced a definition of mechanically tenderized beef as well as the requirement that it be clearly labeled, including safe cooking instructions for consumers.

In addition to this food labeling initiative, Health Canada is currently in the process of consulting with consumers on ways to improve nutritional information presented on food labels as well as proposing to introduce regulations to enhance the labeling of priority allergens in foods.

Our aim is to support the health of our people and we want to ensure that we are doing everything necessary so that Canadians can feel confident that the food that they are feeding their families is safe and healthy.

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 for 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 our provincial regulators ensures that 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 labeling directions.

Tackling prescription drug abuse is another one of our government's priorities as this continues to be a very pervasive issue. The statistics over the last couple of years speak volumes. In 2012, the Canadian Alcohol and Drug Use Monitoring Survey indicated that approximately 410,000 Canadians reporting reported abusing psychoactive pharmaceuticals in the past year, more than double the numbers in the previous year.

In 2012, about one million youth between the ages of 15 to 24 years reported having used a psychoactive pharmaceutical in the past year. And about 210,000 of those youth also reported having abused these substances.

As announced by our government, we are committed to expanding the scope of the National Anti-Drug Strategy to address prescription drug abuse. In January of this year, our Minister of Health co-hosted a symposium including officials from the different levels of government, doctors, pharmacists, first nation representatives, law enforcement, and addiction specialists to discuss prescription drug abuse.

The symposium focused on identifying actions to address prescription drug abuse under the three action plans of the National Anti-Drug Strategy which are prevention, treatment, and enforcement. It was recognized that addressing prescription drug abuse is a shared responsibility. And we strongly believe that working with our partners and stakeholders is essential to our success in dealing with this pervasive issue.

I would also like to take a moment to share with you some of our activities in our Inspectorate Program that relate to the quality assurance of drug products via good manufacturing practices. 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.

The extension of GMPs to include identification of active pharmaceutical ingredients has increasingly been recognized as a necessary element in ensuring the overall quality and the consistency of marketed drug products.

In May of last year, Canada's Food and Drug Regulations were updated to extend these requirements and the amendments came into force last November. These requirements will apply to all active ingredients, manufacturers, packagers, labelers, and importers. Work is currently underway with Canadian companies to help them better understand their new responsibilities in manufacturing drugs as we continually strive to improve the safety and quality of Canadian drug products.

In Canada, the use of marijuana has not been legalized for recreational purposes. Since 2001, Health Canada has granted access to marijuana for medical purposes to Canadians who have had the support of their physicians.

Under the regulations in place at the time, individuals had three options for obtaining a legal supply of dried marijuana. They could apply under the regulations to access Health Canada supply of dried marijuana, they could apply for a personal use production license, or they could designate someone to cultivate on their behalf with a designated-person production license.

However, in response to concerns raised by stakeholders nationally with regard to this system being open to abuse and after extensive consultations, the government of Canada introduced the new Marijuana for Medical Purposes Regulations in June of last year. The new regulations aim to treat marijuana as much as possible like any other narcotic used for medical purposes by creating conditions for a new commercial industry that is responsible for its production and distribution.

Shifting to regulatory modernization which we heard about from our previous presentation by our colleagues from the FDA, regulatory modernization is another one of our key priorities. We continue to work on our Regulatory Roadmap for Health Products and Food that provides a vision of transformation; where we are, where we are going, and how we're going to get there.

Essentially, the roadmap provides the vision to transform nearly a dozen current frameworks for food and health products and of various ages and regulatory approaches into a more efficient, transparent, and comprehensively aligned regulatory system that contributes directly to the safety of Canadians.

Throughout the process of transformation, a key commitment within the Roadmap strategy is to work openly, transparently, and meaningfully with Canadians, stakeholders, and partners as we move forward with our plans for modernization. This initiative has required several phases in order to fulfill our obligations of regulatory reform. And we anticipate that full and complete implementation of all phases will be a few years down the road.

An important element of regulatory modernization is ensuring that Canadians are informed and engaged throughout the process so that the policies we create are reflective of the needs of our people and the environment that we're operating in. Greater transparency and openness build confidence and trust in the regulatory decisions that we are making and enforcing.

Just this past April, our Minister of Health announced the launch of the Regulatory Transparency and Openness Framework for Health Canada. This is part of the Open Government initiative launched in 2011 by our government and demonstrates our commitment to transparency when making regulatory decisions.

The Framework and its accompanying Action Plan lays out our three main goals; to make information easier to understand for Canadians, making more information available, and making decision-making processes more transparent overall.

Our regulatory efforts play a significant role in ensuring that Canadians are able to make informed and healthy decisions. So assuring access is key. For example, when we make our drug safety reviews public, patients and medical professionals can make informed decisions and continue to have confidence in the health products that they are using.

As we all know, regulators are facing an increased challenge of managing the resources in a sustainable way that also provides an appropriate level of oversight for existing products yet responsive to advances in science and changes in the marketplace.

Regulatory reform, while moving forward towards greater and global cooperation, will provide a means for the regulator to regain and maintain sustainability and flexibility. Our government has taken measures to assure that our regulatory reform is not only transparent but also includes reducing administrative burden on industry and encouraging investment and innovation that contributes to a robust economy.

Our Regulatory Roadmap for Health Products and Food recognizes that international partnering is necessary to regulate food and health products in a sustainable way given the interconnected nature of the food and health product industries and their increasingly complicated supply chains. The roadmap lays out the benefits of a shared approach and aligns the current Government of Canada initiatives to find ways to reduce and prevent regulatory barriers.

The Regulatory Cooperation Council, which was created in 2011 between our two countries, is an example of regulatory cooperation at its best. The aim of the RCC is to better align our regulatory systems, reduced unnecessary duplications and differences, and where feasible, leverage our resources in a more efficient and effective manner. The results that we're seeing to date demonstrate the tangible benefits to stakeholders, to consumers and regulators and also to us as regulatory partners.

For example, the common electronic submissions gateway which I'll speak about on the next slide provides industry with a more streamlined and efficient mechanism to support the health product review process. Proposals are being explored and developed which outline joint delivery and regulatory cooperation in the areas of mutual benefits such as personal care products and pharmaceuticals for health and animal use.

Our goal is enhanced collaboration on enforcement and compliance by increasing mutual reliance on each other's routine surveillance practices so we can avoid duplication. This is a common sense approach for us as a smaller entity to the United States and we believe that we can continue to advance and address the barriers between our two jurisdictions. We'll continue to build on this work as we move forward

in addition to other initiatives such as the Red Tape Reduction Commission that aims to remove administrative burdens to industry while continuing to protect the integrity of our regulatory oversight frameworks.

Canadian regulators and scientists have made a significant contribution towards the goal of international cooperation. Participation with international partners through intergovernmental exchange reforms has resulted in improved alignment and efficiency of our regulatory systems as well as opportunities for us to leverage our limited resources amidst increasing economic pressures.

Further, promoting Health Canada's cooperation internationally will continue as a priority and a factor in developing our regulatory framework moving forward.

An important aspect of collaboration for us is having the tools in place to facilitate access, efficiency, and coordination. With globalization, millions of products, health products, and foods are traded between our countries every day. As noted, there has been much work already undertaken between our two countries. Collaboration between Health Canada and the US-FDA on GMP compliance and enforcement is a good example of import sector collaboration.

This is an initiative under the Regulatory Cooperation Council whereby we work towards identifying mechanisms of possible regulatory alignment and mutual reliance in such areas as product review and inspection of manufacturing facilities as well as establishing requirements and standards where appropriate.

Some of the tangible benefits include eliminating duplicative inspections in the other country, exchanging inspection and compliance information regarding sites of common interests and developing a greater understanding of each agency's respective regulatory systems and operational frameworks.

An example of what that looks like in terms of practice includes observational inspections that took place last year, whereby Health Canada and the FDA performed four observational inspections comprised of two in Canada and two in the US. Each agency led an inspection in each country while the other agency observed. This initiative has provided a great opportunity to learn about each agency's processes and regulatory structure and the work that's ongoing.

On a slightly different level, a similar exchanged happened last year among our executive level officials between the FDA, CFIA, and Health Canada as well as both US and Canada border officials at the second Annual Border Officials meeting in North Dakota. It was a great opportunity to share information about inspection activities and how we can continue to connect with one another and coordinate these activities overall. There is a follow-up session that's also planned for this July.

So in moving forward, Canada and the United States have a strong record of achievement in regulatory cooperation. Both countries are committed to working together to one another's mutual benefit. And though I have just outlined a couple of examples, there are many more that exist and I would encourage us to continue to explore those in moving forward between our regulatory agencies.

Finally, I really would like to articulate that the work that we have undertaken, the opportunity for Health Canada and for our CFIA colleagues to participate in AFDO is a critical element in sharing information, best practices, getting a better understanding of your regulatory requirements and again, how we can realign those. I think we heard yesterday morning from Dr. Atchison about the benefits of collaboration and particularly amongst trusted trading partners and partners that are attempting to move to a greater alignment with regard to border activities. We hope that we'll continue to build on those relationships and to strengthen the work moving forward.

So on behalf of Health Canada, I'd like to thank the AFDO organizers for once again providing us an opportunity to update you on Health Canada's activities and priorities. And I hope over the next day or so between myself and my other colleagues from Health Canada, if you have any questions or opportunities again, to work collaboratively, we would certainly welcome the chance to have that discussion. Thank you very much.

[Applause]

[End of transcript]

CFIA Update
Transforming the Canadian Food Inspection Agency (CFIA)
Stephen Baker, Vice President, Operations Branch, CFIA
AFDO 118th Annual Educational Conference
Denver, CO – June 24, 2014

Thank you. It's a pleasure to be here. Today, I'm going to provide you with a brief overview of the CFIA, how we are organized and what we do, and most importantly how we are transforming ourselves as we move into the future.

I know many of you will be familiar with the Canadian Food Inspection Agency – the CFIA. We are a federal government regulatory agency responsible for safeguarding Canada's food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy. Our headquarters are in Ottawa, Ontario, Canada, and our staff totals approximately 7,000 people.

In terms of inspection delivery, we have a large geographic area to cover. We have organized ourselves into 4 areas (Atlantic, Quebec, Ontario, and the West), 18 regions and 118 district offices.

Of late, the CFIA has embarked on an ambitious transformation agenda which has about a 5 year horizon. My role, as the Vice-President of the Operations Branch within the CFIA, has been to be a leader in the operational context for that transformation.

So what do we mean by a "transformation". It's a fairly dramatic word. Transforming the CFIA is a modernization process that aims to strengthen our legislative foundation, regulatory programs and inspection delivery. It is focused on stronger safety rules, more effective inspection, a commitment to service and providing more information to consumers.

Our broad-based transformation agenda is designed to foster improvements in food safety to meet the growing challenges posed by a complex global food environment.

We are working toward a preventive system that enables industry and the CFIA to more effectively and consistently manage risk and resources.

And why are we embarking on this transformation? Well, we are all familiar with a changing world environment - globalization, and the idea that industry is moving quickly and that regulators need to keep pace. The environment in which we operate is continuously evolving. Our regulated parties are very sophisticated now. International and national companies are more common than smaller and local enterprises and the risk that their products represent is different than it has been in the past.

So we have to find a way to deal with these changes effectively. And what we have done is to design a transformation agenda to modernize and bring us to where we need to be, to be relevant, efficient and effective.

Our transformation agenda can really be described using two themes: regulatory and legislation modernization and business/inspection modernization.

In terms of modernizing Canada's food legislation, you may know that the Safe Food for Canadians Act (SFCA) received Royal Assent in 2012, providing the legislative base to simplify and consolidate our regulations and make them outcome-based with common requirements across commodities.

The Food and Drugs Act (FDA) will continue to apply to all food sold in Canada, as do other CFIA statutes related to plant and animal health.

Modernizing our regulations will enable a science and risk-based approach, allowing a focus on prevention and control of potential hazards while being robust and responsive to emerging issues.

Our proposed approach to new regulations is largely aligned with the US Food and Drug Administration draft rules under the FSMA.

The timing of the Canadian and US food safety initiatives presents an opportunity to pursue coordinated regulatory approaches that could enhance consistency between our respective food safety regulations. We are interested in what is going on down here.

The second broad theme is the notion of modernizing our business model. We have examined key business functions, and will be implementing changes in the following areas: risk assessment, program management, licensing, inspection activities, exports, imports, control and enforcement activities.

We have begun with the premise that to modernize we need to systematically and centrally assess risk. Building on the notion of risk assessment, centralised risk assessment, is that we can build models and ways to analyse that risk that will allow us to predict where the risk is highest in a commodity and we will apply inspection resources appropriately.

And we plan to centralize administration. What we intend to do is to centralize and automate wherever we can so that we have inspectors spending their time doing compliance verification and enforcement activities.

We are also working to centralize and automate our export approval process.

When it comes to imports, the CFIA is part of the single window initiative. The single window is a portal for all importers to use to come into Canada and the CBSA, Canadian Border Service Agency, is coordinating that initiative.

An important element of our business transformation is transparency. We are consistently being asked to provide much more information to Canadians.

Another element is the notion of compliance and compliance promotion. Compliance promotion is an activity which we're delving into. It involves more concrete comprehensive education, and outreach to regulated parties.

In addition to modernizing our legislation, regulations and business approaches and systems, the CFIA's inspectorate will need to evolve, adapt and change in order to deliver inspection in a modernized environment.

CFIA inspectors – known collectively as the inspectorate – are responsible for making compliance and enforcement decisions. Their decisions are essentially about the issuing and maintenance of permissions. These permissions are to do with producing food importing, exporting and taking enforcement actions when parties do not comply with the regulation and policies of the Government of Canada.

We are looking at ways to provide the inspectorate with different and better ways of being trained, we intend to enable them with technology that allows for increased flexibility and mobility, and we have taken steps to make sure they are provided with predictable and consistent advice to inform their decision making.

Let's start with training. One of the things we've done is to take steps to centralize our training system. Eventually, we hope to have a model where we will train all the inspectors through something like the IFPTI (International Food Protection Training Institute) framework so that there's a consistent hierarchy of competence and certification. We want inspectors to have clear career paths and to understand how they can progress through those paths. This centralized approach will allow us to provide common basic knowledge across the inspectorate with the focus being mainly on how to be a good inspector and less on commodity specific information.

Another major element of modernizing the inspectorate is automation. We are working to provide an inspection management system which will be a case-based tool. It will replace up to 30 legacy systems that we currently use to manage the inspection space and that automation will allow inspectors to be mobile and effective.

And finally, the notion of a clear written advice. Providing consistent, understandable guidance to the field is essential, and we are organizing ourselves to do that and to build the business processes to make that happen.

The part I really want to talk about is culture. One of the things we realized early on in this process was that we don't have a single culture in our inspectorate. We define culture as a set of behaviors that reflect a core set of beliefs.

We put a lot of thought into this and did a lot of work and consultation. And we decided we needed to work hard at creating a single culture in the inspectorate across all the regions and all the commodities in the country. We're looking at trying to find a way for the inspectors to understand what is expected of them.

And we landed on three words to describe our desired culture: courage, rigor and respect. The courage to make a decision based on established procedures and guidance and provide fearless advice in the face of opposition. Rigor to deliver responsibilities with thoroughness, diligence and consistency. And respect – to always act respectfully towards regulated parties.

Looking to the future, we are undergoing significant change. And we realize this change will not happen until something happens – nothing changes until it changes.

Let's turn to the next steps for us in our transformation. Regulatory modernization is ongoing. We expect that the new regulations will be before Parliament this fall and anticipate they will be enabled in 2015.

Our business modernization continues and we expect that in undergoing our transformation process we will build on our successes and we will capitalize on what works. We will make changes where we can and where we need to, to be modern, flexible and able to react to situations consistently and predictably. And in doing so, we aim to ensure that our organization remains relevant, reliable and responsive – today and in the years to come. Thank you.

USDA Update
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USDA – Progress, Trends, and Compliance
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The following article comes from the “FSIS Best Practices Guidance for Controlling *Listeria monocytogenes* (Lm) in Retail Delicatessens - April 2014”

Introduction

Lm is a bacterium that is found in moist environments, soil, and decaying vegetation and can persist along the food continuum. Transfer of the bacteria from the environment (e.g., deli cases, slicers, and utensils), employees, or raw food products is a particular hazard of concern in RTE foods, including meat and poultry products. Listeriosis is a serious infection usually caused by eating food contaminated with Lm. Controlling Lm has long been an objective of the public health community. The Centers for Disease Control and Prevention (CDC) estimates that infection with Lm causes about 1,600 illnesses, 1,500 hospitalizations, and 260 deaths in the United States each year. Listeriosis is rare, but its fatality rate is very high (about 16 percent, compared with 0.5 percent for either *Salmonella* or *E. coli* O157:H7) (Scallan et. al., 2011). It primarily affects older adults, pregnant women, newborns, and adults with weakened immune systems.

Lm can survive and grow at cool temperatures (as low as 34° F/1°C). Because of its growth and survival characteristics, Lm is usually persistent in the environment and is commonly referred to as a harborage organism (i.e., it can form niches and grow to high numbers in the environment; niches provide an ideal place for Lm to establish and multiply). It can cross-contaminate food contact surfaces and foods. Improper sanitation, product handling, and employee practices can lead to the transfer of Lm to RTE meat and poultry products at retail, causing them to become adulterated (see Regulation of Meat and Poultry Products at Retail below).

RTE meat and poultry products do not require cooking prior to being consumed and are often held at refrigerated temperatures. Once contaminated with Lm, RTE food products may provide an ideal environment for this harmful bacterium to grow. A variety of retail surveys of deli meats and a number of risk assessments of Lm in deli-sliced versus pre-packaged deli meats have analyzed the risk of listeriosis associated with deli prepared meat and poultry products. The FSIS Comparative Risk Assessment for Lm in Ready-to-eat Meat and Poultry Deli Meats (May 2010) estimated that of listeriosis illnesses attributed to deli meat, 83% are associated with deli meat sliced and packaged at retail (Endrikat et al. 2010).

Safe food handling practices, thorough cleaning and sanitation procedures, maintenance of the facility and equipment, and good employee practices are key components that may prevent or reduce the likelihood of RTE foods becoming contaminated in retail delis.

Regulation of Meat and Poultry Products at Retail

FSIS shares jurisdiction at retail with FDA and State, local, and tribal authorities for meat and poultry. FDA makes recommendations regarding retail practices through the FDA Food Code. The Food Code is used by the State and local agencies as a model to establish regulations, ordinances, and actionable policies that can be enforced in their jurisdictions. Operators of retail establishments are required to comply with the conditions of the permit or license under which they operate.

The Federal Meat Inspection Act and Poultry Products Inspection Act apply to meat and poultry products produced in federally inspected establishments and other entities producing or handling meat and poultry, including at retail. Although retail firms are generally exempt from FSIS inspection, retailers are required to maintain sanitary conditions and otherwise not produce adulterated or misbranded product (21 U.S.C. 623(d) and 464(e); 9 CFR 303.1(f) and 381.10(d)(4)). The types of operations that are traditionally and usually conducted at retail stores can be found in 9 CFR 303.1(d)(1) and 9 CFR 381.10(d)(1).

FSIS provides instructions to its personnel for surveillance activities at retail in FSIS Directive

8010.1. The purpose of in commerce surveillance is to ensure that FSIS-regulated meat and poultry distributed in commerce are safe, wholesome, and not adulterated; are correctly marked, labeled, and packaged; are secure from intentional acts of contamination; and are legally imported and properly exported. When performing in commerce surveillance, FSIS verifies that:

1. Meat and poultry are wholesome and not adulterated;
2. Sanitary conditions are such that meat and poultry will not become contaminated with filth or rendered injurious to health;
3. Hazard controls are adequate to prevent meat and poultry from becoming adulterated;
4. Meat or poultry not intended for use as human food are properly denatured or otherwise made inedible as prescribed by the regulations; and
5. All records are kept and maintained in a manner that fully and correctly discloses all transactions involved in the business activity that is subject to the provisions of the Acts.

This guidance does not replace the FDA Food Code, State, tribal or local, or FSIS regulations. This document can be used along with the 2013 FDA Food Code to help retailers ensure that meat and poultry products are not prepared or sliced under

insanitary conditions in the retail deli area, which can lead to Lm contamination and outgrowth of the organism on the product.

The Interagency Retail Lm Risk Assessment Findings

The Interagency Retail Lm Risk Assessment was jointly developed by FSIS and FDA, and in consultation with the CDC, to help guide food safety efforts to minimize the public health burden of listeriosis in the U.S. The risk assessment was conducted to better understand how retail practices (e.g., temperature control, sanitation, worker behavior) influence the public health risk of listeriosis associated with eating meat, cheeses, and salads sliced or prepared in retail delicatessens. It also examines how effective various interventions are in limiting the survival, growth, or cross contamination of Lm.

The risk assessment is based on observations of deli employees' work routines; concentrations of Lm on incoming products and in the deli environment; studies on the ability of Lm to spread in retail delis, such as from a slicer to food; and an existing dose-response model. The study was designed to apply to a range of deli establishments, from small independent operations to the deli departments in large supermarkets.

The risk assessment also reinforces the importance of FDA's Food Code recommendations to operators of retail delis. State, local, and tribal jurisdictions can do their part to reduce listeriosis by enforcing all relevant provisions of the 2013 FDA Food Code as part of their own food safety requirements.

The risk assessment found that certain practices are needed to effectively prevent cross-contamination and limit Lm growth in RTE foods handled or prepared in retail delicatessens, including proper storage, adequate sanitation, and effective employee practices.

NOTE: This guidance document includes key findings from the Interagency Retail Lm Risk Assessment and provides an overall summary of the data for typical retail deli settings. More detailed information regarding the findings is in the risk assessment report.

Key Findings

The following are key findings of the Interagency Retail Lm Risk Assessment for typical retail deli settings.

- **Storage Temperature.** If all refrigerated RTE foods are stored at 41°F (5°C) or below, as the 2013 FDA Food Code (3-501.16(A)(2)) recommends, approximately 9% of predicted listeriosis cases caused by contaminated deli products prepared or sliced in the retail deli could be prevented.
- **Growth Inhibitors.** If all deli products that support Lm growth were reformulated to include growth inhibitors, approximately 96% of predicted listeriosis illnesses caused by RTE products prepared or sliced in the retail deli could be prevented. While this finding is significant, the actual benefit may be smaller in part because the concentration of the growth inhibitor used may not be sufficient to be effective throughout the shelf life of a food or may not

be used in high enough concentrations because the inhibitors can adversely affect the flavor of the product.

- **Control Cross-Contamination.** The predicted risk of listeriosis dramatically increases in retail delis as a result of cross-contamination. In particular, slicers are key sources of cross-contamination in retail delis. Eliminating all points of cross-contamination in the deli (including slicers) would decrease the predicted risk of illness from the consumption of RTE products prepared or sliced in the retail deli by approximately 34%. Cross-contamination is particularly difficult to control completely; however, the risk assessment shows that proper product handling, cleaning, sanitizing, and glove use help prevent cross-contamination.
- **Control Contamination at its Source.** Increased levels of Lm from incoming products and the environment (including potential niches), directly increases the predicted risk of illness. Therefore, elimination of environmental niches in the deli area will reduce the predicted risk of listeriosis from the consumption of RTE products prepared or sliced in the retail deli. Additionally, if levels of Lm on RTE foods (including foods that do not support the growth of Lm) that the retail deli receives from processing establishments were reduced by half, approximately 22% of the predicted listeriosis illnesses caused by contaminated deli products could be prevented. This finding suggests that continued efforts to prevent low levels of Lm contamination during processing, even on products that do not support growth of the pathogen, reduces the predicted risk from these products and other RTE foods that can be subsequently cross-contaminated in the retail delis.
- **Continue Sanitation.** Sanitation practices that eliminate Lm from deli food-contact surfaces result in a reduction in the predicted risk of illness. Cleaning and sanitizing food-contact surfaces reduces the predicted Lm levels in the deli area. Employees not wearing gloves while serving customers increases the predicted risk of listeriosis from the consumption of RTE products prepared or sliced in the retail deli by approximately 5%.

How to Use this Guidance

This guidance provides practical recommendations that retailers can use to control Lm contamination and outgrowth in the deli area based on the findings of the Interagency Retail Lm Risk Assessment, available scientific knowledge, the 2013 FDA Food Code, as well as lessons learned from controlling Lm in meat and poultry processing establishments. Retailers can use this best-practices guidance to help ensure that RTE meat and poultry products in the deli area are handled under sanitary conditions and are not adulterated under the FMIA and PPIA. While these practices are designed to control Lm specifically, they also may help control other food borne pathogens that may be introduced into the retail deli environment and other facilities where consumers take possession of food.

The best practices are divided into four sections: (1) product and product handling, (2) cleaning and sanitizing, (3) facility and equipment controls, and (4) employee practices.

Practices identified by the risk assessment that can significantly decrease the predicted risk of foodborne illness are highlighted in each section. The other practices that are based on scientific knowledge or lessons learned also will help retailers increase Listeria control in the deli area. For example, although floors and drains were not considered as a source of cross-contamination according to the Interagency Retail Lm Risk Assessment, FSIS data has shown that floors, drains, and items like floor mats tend to be harborage points in FSIS establishments. Providing this information can assist retailers in controlling Lm in the deli area. A self-assessment tool is provided for deli operators to help them identify the best practices they are using and to assess if they need to adopt others. By following the best practices in the guidance and the 2013 FDA Food Code, retailers can help ensure that RTE products are not adulterated with Lm, and that the potential for listeriosis is decreased.

NOTE: Retailers should be aware that the recommendations in this guideline, especially those based on the 2013 Food Code may be requirements in State, local, or Tribal regulations. Questions on this guideline should be submitted through askFSIS.

Product Handling

The Interagency Retail Lm Risk Assessment found that using practices that prevent bacterial growth in the product substantially reduced the predicted risk of listeriosis. In addition, while the risk assessment showed that the risk from incoming Lm-contaminated products that do not support growth is low, it also showed that these products can cross-contaminate RTE products that support growth, and when they do, the risk increases substantially. The formulation of RTE products with antimicrobial agents prevents growth of Lm in RTE foods both at retail and during consumer home storage, leading to an overall reduction in the predicted risk of listeriosis. The 2013 FDA Food Code (3- 501.16(A)(2)) recommends keeping RTE products at or below 41°F (5°C), which slows the growth of Lm in the deli and decreases the predicted risk for listeriosis. Other scientific studies also have shown that preventing product contamination reduces the risk of foodborne illness.

Therefore, it is important for retailers to adopt practices that protect RTE product from contamination with Lm and to use strategies to prevent or limit the growth of Lm in deli product. Below are a few such strategies.

- Use products formulated with antimicrobial agents (e.g., acetic acid, sodium diacetate, lactic acid, citric acid) when possible, to eliminate or prevent the growth of Lm in RTE products. In some cases, the addition of antimicrobial agents may not be possible because of the adverse effect on the flavor of the products. Retailers can read the ingredients statements on the labels to see whether the products in the deli have antimicrobial agents and can contact their suppliers to determine whether products formulated with antimicrobial agents are available.

NOTE: As stated previously, the Interagency Retail Lm Risk Assessment estimated that if antimicrobial agents are used in all products in the deli, the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail departments could be decreased by approximately 96%.

- Use products that have been treated to reduce pathogens (e.g., through high pressure processing (HPP)). This information can be determined from certificates of analysis (COA), letters of guarantee (LOG), or other information from suppliers. Separate products that support growth from products that do support growth (when possible) to help prevent cross contamination.

NOTE: As stated previously, the Interagency Retail Lm Risk Assessment found that if current levels of Lm in RTE foods (e.g., meats, cheeses, and salads) received by the retail deli were reduced by half, the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments could be decreased by approximately 22%.

- Monitor the shelf life of an RTE product opened, prepared, and held in a retail setting for more than 24 hours. To monitor shelf life of the opened product, retailers should date- mark the product (e.g., clearly mark it with the date of opening and the discard date) as recommended by the 2013 FDA Food Code (3-501.17). Products also should be properly identified and labeled. RTE products that are past their shelf life should be discarded.
- Do not pre-slice products in the morning, after cleaning. Retailers should slice the product at the time it is requested by consumers.

NOTE: The Interagency Retail Lm Risk Assessment found that pre-slicing the product increases the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments by approximately 6%.

- Remove products that are filthy, putrid, decomposed, slimy, rancid, or in off-condition, which are likely to be considered adulterated, from the deli area as soon as possible. Thoroughly clean and sanitize areas that were contacted by the affected product to prevent any cross-contamination.
- Promptly return RTE products to refrigerated units, after slicing, to prevent pathogen growth. Maintain refrigeration units at or below 41°F (5°C) to slow the growth of Lm, as recommended by the 2013 FDA Food Code (3-501.16(A)(2)). RTE products should be covered, wrapped, or otherwise protected to prevent cross-contamination when not in use.

NOTE: The Interagency Retail Lm Risk Assessment found that storing the products at or below 41°F (5°C) decreases the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments by approximately 9%.

- Store and handle RTE products in a separate area from raw products. RTE products that are prepared, held, or stored near raw products can become contaminated (e.g., because of aerosolization or dripping). The 2013 FDA Food Code (3-302.11(A)(1)) recommends that retailers separate RTE foods from raw foods. If storage space is limited, wrap the products and store RTE products above raw products. When wrapping, unwrapping, and slicing products, take care to prevent cross-contamination from the outer wrapper, other products,

and unclean surfaces and utensils. Raw products (e.g., chicken used for frying or rotisserie) prepared in the same area as RTE products can increase the potential for cross-contamination.

- Clean and sanitize surfaces between RTE items when using the same equipment to cut, slice, or otherwise reduce the size of large RTE products (e.g., ham, seafood, and vegetables).
- Ensure that grinders, dicers, or other equipment are maintained in sanitary condition when preparing deli salads.

Things to Consider at Retail

- ✓ Are the deli products being sold formulated with antimicrobial agents?
- ✓ Is RTE product properly identified and labeled?
- ✓ Are RTE products identified with the date the package is opened?
- ✓ Is RTE product discarded if it is past the recommended discard date?
- ✓ Is there a process to routinely remove RTE products that are not suitable for sale from the retail case?
- ✓ Are RTE meat and poultry products promptly refrigerated after use?
- ✓ Are RTE products prepared and stored adjacent to raw product?
- ✓ Is the retail deli case maintained at 41°F (5°C) or below to prevent pathogen growth?
- ✓ Is RTE product covered, wrapped, or otherwise protected after opening?
- ✓ Are RTE products placed on the same contact surfaces as other RTE product, e.g., cheese, vegetables, seafood?

Cleaning and Sanitizing

The Interagency Retail Lm Risk Assessment found that following the sanitation practices in the 2013 FDA Food Code aid in controlling Lm on deli area food contact surfaces and reduces the predicted risk of listeriosis. The 2013 FDA Food Code (4-602.11(C)) recommends cleaning equipment and utensils at least every 4 hours. Below are some key issues to consider when cleaning and sanitizing.

- Develop written sanitation procedures that describe how utensils and equipment (e.g., slicers) will be cleaned and sanitized daily prior to use. Ensure employees are familiar with and follow these procedures to reduce the risk of contaminating RTE products with Lm. Insanitary conditions (e.g., flies, rodent droppings, mold, or dirty surfaces) should not be present in retail areas.

Retailers should **document** the actions they perform to ensure that sanitation procedures are performed on a regular basis.

NOTE: The Interagency Retail Lm Risk Assessment found that the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments increases by approximately 41% if wiping, washing, and sanitizing activities are not performed.

- Clean and sanitize utensils and equipment used to handle, prepare, and store RTE products frequently (e.g., at least every 4 hours as recommended by the 2013 FDA Food Code (4-602.11 (C)) to maintain sanitary conditions throughout the day. Clean and sanitize items that employees routinely handle, such as on/off switches, slicer handles, display cases, cooler handles, and similar surfaces.

NOTE: As stated previously, the Interagency Retail Lm Risk Assessment found that slicers are sources of Lm cross-contamination to RTE foods. Control of Lm cross-contamination at all points (including slicers) during retail preparation and handling of RTE foods would reduce the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in retail deli departments by approximately 34%.

- Disassemble RTE food-processing equipment to clean and sanitize on a regular basis to ensure that hard to reach areas where Lm can hide are addressed. For more information, see the FDA poster: *Keep Commercial Deli Slicers Safe*.
- Follow the manufacturer's recommendations for sanitizer strength and application to ensure it is effective. Many sanitizers, when used as recommended, are effective against Lm, including those containing quaternary ammonia compounds, chlorine solutions, and organic acids. Generally, increasing the sanitizer strength above the recommended levels will not increase the efficacy of the sanitizer and may result in harmful levels of the sanitizer in foods.
- Change sanitizers as needed to provide more effective bacterial control. Lm and other bacteria can adapt to the environment over time and can form biofilms, which are thin layers of microorganisms that adhere to product contact surfaces. Biofilms are difficult to remove, and they may protect Lm from the effects of sanitizers. Alternating sanitizers (e.g., quaternary ammonia and bleach) may help prevent Lm from developing resistance to sanitizers and forming biofilms.
- Develop a procedure to sanitize cleaning aids or have single-use items that are discarded after use. Cleaning cloths, brushes, sponges, mops, and similar cleaning aids can become contaminated with bacteria and then can spread the bacteria to every surface they contact. Therefore, cleaning cloths and other items should be cleaned of visible material and soaked in clean sanitizer between uses. Retailers should monitor sanitizer strength and change the

sanitizer as needed so that food particles do not overwhelm the effectiveness of the sanitizer.

- Use low water pressure when cleaning in the deli areas. Splashing and overspray from high-pressure hoses can aerosolize microorganisms and distribute them into the air and onto nearby surfaces.
- Use separate sinks for hand washing and cleaning product or equipment (as recommended by the 2013 Food Code (2-301.15 and 4-501.16)). Hand washing can cause the sink to be contaminated with Lm and other pathogens, which can be spread to any other items cleaned in the sink.
- Eliminate or remove unnecessary items (such as supplies and equipment) from the deli area. Organize supplies and equipment to facilitate thorough cleaning.

Things to Consider at Retail

- ✓ Are sanitation procedures documented?
- ✓ Are RTE product contact surfaces cleaned and sanitized prior to use?
- ✓ Are routine cleaning and sanitation procedures performed in areas where RTE products are handled, stored, and sold?
- ✓ Is RTE equipment disassembled before cleaning and sanitizing?
- ✓ Are sanitizers used at the recommended concentrations?
- ✓ Are sanitizers rotated on a periodic basis?
- ✓ Are cleaning cloths rinsed or soaked in sanitizer between uses?
- ✓ Are only low-pressure water sources (hoses) used during cleaning to prevent splashing?
- ✓ Is the deli area free of debris and unnecessary materials that make cleaning difficult?

Facility and Equipment Controls

The Interagency Retail Lm Risk Assessment found that increasing the level of Lm and the potential of cross-contamination increases the predicted risk of listeriosis. The 2013 FDA Food Code (6-101.11(A)(1)) recommends that floors, walls, and ceilings be smooth, durable, and easily cleanable. Facilities, equipment, and utensils should not contribute to product adulteration or contamination. Here are some areas to check and some insanitary issues to avoid.

- Do not allow conditions in the retail facility that could cause the product to become adulterated. These could include condensation dripping on exposed product, construction dust on product or food contact surfaces, or broken equipment.
- Ensure that walls, floors, drains, and overhead structures in the RTE deli and cooler areas are smooth, durable, easily cleanable, and in good repair. Rubber floor mats and other items used on the floor may be harborage sites for Lm. Clean them as often as necessary to ensure that sanitary conditions are maintained.
- Do not perform construction (e.g., replacing floors, walls, or ceilings) when exposed RTE product is present in the deli. Lm can be harbored behind the walls and carried by dust. Therefore, the product should be protected during construction, and the deli area should be cleaned and sanitized after construction and before use.
- Maintain tables, slicers, and other food contact surfaces so that they are easily cleanable. Rough surfaces created by welds, cracks, and other defects can be difficult to clean and can create areas where bacteria can hide. Worn, missing, or degraded seals or gaskets should be replaced because they may become contaminated with Lm.
- Clean overhead structures as often as necessary to keep them free of condensation and ensure that sanitary conditions are maintained. Overhead items (e.g., cracked light fixtures) can be Lm harborage points. Condensation on overhead structures can lead to contamination of food or food preparation surfaces.
- Keep water from pooling on the floor or other surfaces within the deli area. Doing so will reduce the likelihood that splash could contaminate food products or food contact surfaces. Standing water can serve as a vehicle for Lm and other pathogens.

Things to Consider at Retail

- ✓ Is the facility structure in good repair to prevent contamination or adulteration of products in the deli area?
- ✓ Is the equipment nonporous and free of cracks, pits, and rough welds?
- ✓ Is the overhead structure in the deli area free of condensation?
- ✓ Is the deli area free of standing water on floors or product contact surfaces?

Employee Practices

As mentioned previously, the Interagency Retail Lm Risk Assessment found that wearing gloves while serving customers reduces the predicted risk of listeriosis. The 2013 FDA

Food Code also recommends that employees wear gloves or use other suitable utensils to handle RTE foods and includes recommendations for training, hand washing, employee health and hygiene, and limiting public access in deli areas to prevent product contamination (references below). Good employee hygiene practices are critical to prevent cross-contamination and the spread of Lm and other pathogens. Lm can be present on, and spread by, equipment, materials, foods, and people. Here are a few employee practices retailers can use to minimize cross-contamination.

- Ensure that employees wear gloves or use suitable utensils when handling RTE products, as recommended by the 2013 FDA Food Code (3-301.11(B)). Provide **disposable gloves** so that employees wear and change gloves, as needed, to prevent the contamination of food.

NOTE: The Interagency Retail Lm Risk Assessment found that employees not wearing gloves increases the predicted risk of listeriosis from the consumption of RTE products sliced or prepared in the retail deli department by approximately 5%.

- Train employees in sanitation practices and safe food handling procedures. Ensure that the manager has knowledge of food safety practices and procedures, as recommended by the 2013 FDA Food Code (2-102.11), and that employees have been properly trained in hygienic practices.
- Provide adequate facilities, including soap and running water, for employees to wash their hands. As recommended by the 2013 FDA Food Code (2-301.14), employees should wash hands prior to gloving, when switching between handling raw and RTE foods, after engaging in other activities that may contaminate the hands (e.g., handling money or potentially dirty or contaminated surfaces), or using the restroom.
- Implement a policy to ensure that ill employees do not work with open food items, including RTE foods. For example, written procedures should include removing workers from the deli when they are ill with respiratory or diarrheal diseases, as recommended by the 2013 FDA Food Code (2-201.11).
- Limit traffic in the deli area and develop traffic-flow plans for product, employees, and other items to prevent contamination by consumers and employees. The plans should minimize exposure of open RTE foods to raw foods, exterior packaging, and other possibly contaminated materials, such as boxes, trash, and chemicals. Designing facilities and controlling traffic in the deli area to restrict movement of people and material reduces the chance of cross-contamination. Non-deli workers should not handle exposed RTE products.

Things to Consider at Retail

- ✓ Are there procedures to prevent ill employees from working in the food preparation area?

- ✓ Do employees wash hands prior to handling exposed RTE product?
- ✓ Do employees wear disposable gloves when handling exposed RTE product?
- ✓ If employees wear disposable gloves, do they change them, as necessary, to prevent cross- contamination (e.g., after handling raw product or money) when handling RTE product?
- ✓ Is foot traffic limited in RTE food product handling areas?

Deli Self-Assessment Tool

Retailers should use this tool to determine whether they have adopted the appropriate procedures to control Lm or should adopt new procedures. The preferred answer (based on the information in the guideline) is indicated with an asterisk. Having a “no” answer does not necessarily indicate lack of control. If retailers find that they are not meeting the recommendations in this guideline, they should consider changing practices to better control Lm in the deli area.

Product/ Product Handling: RTE Deli Area	YES	NO	N/A
1. Is any visibly adulterated product present in the area (e.g., filthy, putrid, decomposed, slimy, rancid, off-condition)?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
2. Are RTE meat or poultry products refrigerated promptly after use?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
3. Is RTE product prepared, held, or stored near or adjacent to raw product in the deli case and elsewhere in the deli area?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
4. Is the RTE product date-marked when opened?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there any RTE product in the deli case that is outside of the date-marked period?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
6. Is the deli case maintained at or below 41°F (5°C)?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
7. Is opened RTE product covered, wrapped, or otherwise protected to prevent cross-contamination when not in use in the deli case and elsewhere?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
8. Is RTE product stored in the deli case properly identified and labeled?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
9. Do you use deli products formulated with antimicrobial agents?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
10. Are RTE product contact surfaces cleaned and sanitized prior to using the surface for another product (cross- contamination of products)?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>

11. If you prepare deli salads, are there controls in place to ensure that grinders, dicers, or other equipment are maintained in sanitary condition?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
Cleaning/Sanitizing: RTE Deli Area	YES	NO	N/A
12. Are there insanitary conditions (e.g., flies, rodent droppings, mold, or dirty surfaces) present in areas where meat and poultry products are prepared, packed, or held?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
13. Do you use sanitizers at the proper concentration?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
14. Do you clean and sanitize the RTE equipment (including slicers) at least every 4 hours?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
15. Do you disassemble RTE equipment (including slicers) during cleaning and sanitizing?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
16. Do you soak or rinse cleaning cloths in sanitizer between uses?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
17. Are sanitizer types (e.g., quaternary ammonium, chlorine-based, or iodophores) rotated periodically?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
18. Do you clean the RTE area with a high pressure hose?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
19. Are there separate sinks for hand washing and other uses?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
20. Do you have material (e.g., pallets, milk cartons, cardboard boxes, or push carts) in the deli area that makes cleaning difficult?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
Facility: RTE Deli Area	YES	NO	N/A
21. Are there facility conditions (e.g., condensation dripping on exposed product, construction dust on product, or broken equipment) that could cause the product to become adulterated?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
22. Is there condensation on overhead structures or over the RTE product?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
23. Is there standing water on surfaces, including the floor?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
24. Are product contact surfaces in good condition (e.g., non-porous surfaces, free from cracks, pits, and rough welds)?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
25. Are slicers and mixers in good condition (e.g., free of cracks, broken, missing or unattached parts; seals and gaskets not worn, degraded, or missing)?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
26. Are the walls, floors, and ceilings sanitary and in good repair?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
Employee Practices: RTE Deli Area	YES	NO	N/A
27. Are visibly ill employees working in food preparation areas?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>

28. Do employees work without washing hands prior to handling exposed RTE product?	<input type="checkbox"/>	<input type="checkbox"/> *	<input type="checkbox"/>
29. If employees wear gloves, do they change them as necessary to avoid cross-contamination of RTE product?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
30. Do employees wear disposable gloves when handling exposed RTE product that will not be cooked?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
31. Do employees change outer clothing (e.g., frocks, aprons, or smocks) as often as necessary to avoid contamination of RTE product?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>
32. Is employee foot traffic limited in areas where RTE product is handled?	<input type="checkbox"/> *	<input type="checkbox"/>	<input type="checkbox"/>

*Preferred answer

References and Resources

Burnett SL, Mertz EL, Bennie B, Ford T, and Starobin A. Growth or survival of *Listeria monocytogenes* in ready-to-eat meat products and combination deli salads during refrigerated storage. *Journal of Food Science*. Volume 70, Issue 6, pages m301–m304, August 2005. (Role of temperature in Lm control)

Centers for Disease Control and Prevention website, found at <http://www.cdc.gov/listeria/> (Lm and listeriosis overview)

Conference for Food Protection *Listeria monocytogenes* Intervention Committee. Voluntary Guidelines of Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* Within Food Establishments. (Lm niche and sanitation practices) Found at: <http://www.foodprotect.org/media/guide/2006CFPLmInterventionvoluntaryguidelines.pdf>

Endrikat S, Gallagher D, Pouillot R, Hicks Quesenberry H, LaBarre D, Schroeder CM, and Kause J. A comparative risk assessment for *Listeria monocytogenes* in prepackaged versus retail-sliced deli meat. *Journal of Food Protection*. Volume 73, Issue 4, pages 612-619, April 2010 (FSIS comparative Lm risk assessment)

FDA Food Code, 2013, found at: <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm> (Model regulations, ordinances, and policies for food safety)

FDA/FSIS, Quantitative assessment of relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods, 2003. Food and Drug Administration, United States Department of Agriculture, Centers for Disease Control and Prevention. Found at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm183966.htm> (Lm risk assessment)

Food Marketing Institute (2006). Guidance for the Control of *Listeria monocytogenes* Risks in Retail Food Stores. (Guidance for Lm control)

Food Marketing Institute (2012). FMI Listeria Action Plan for Retail Delis. Found at: <http://www.fmi.org/docs/food-safety-best-practice-guides/listeria-action-plan-for-retail-delis.pdf?sfvrsn=9> (Guidance for Lm control)

FSIS/FDA, Guidelines for Retail and Foodservice Establishments Affected by Natural or Other Disasters, found at: http://www.fsis.usda.gov/wps/wcm/connect/1f4d9cef-3410-4d03-9dd6-08fe089e1317/Fsis_Fda_Retail_Reopening.pdf?MOD=AJPERES (Guidance for retail food safety)

FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products, 2012, found at: http://www.fsis.usda.gov/PDFwps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling_LM_RTE_guideline_0912.pdf?MOD=AJPERES (Guidance for FSIS regulated establishments)

Gibson KE, Koo OK, O'Bryan CA, Neal JA, Ricke SC, and Crandall PG. Observation and relative quantification of cross-contamination within a mock retail delicatessen environment. *Food Control*, Volume 31, Issue 1, pages 116-124, January 2013 (Bacterial cross-contamination in the deli)

Gombas DE, Chen Y, Clavero RS, Scott VN. Survey of *Listeria monocytogenes* in ready-to-eat foods. *Journal of Food Protection*. Volume 66, Issue 4, pages 559-669, April 2003 (Retail surveys of Lm contamination in RTE products)

Lin CM, Takeuchi K, Zhang L, Dohm CB, Meyer JD, Hall PA, and Doyle MP. Cross-contamination between processing equipment and deli meats by *Listeria monocytogenes*. *Journal of Food Protection*. Volume 69, Issue 1, pages 71-79, January 2006 (Lm cross-contamination from slicers)

Lloyd T, Alvarado CZ, McKee SR, and Berrang ME. Control of *Listeria monocytogenes* in ham deli loaves using organic acids. *Journal of Food Safety* Volume 30, Issue 4, pages: 793–803, November 2010 (growth inhibitors)

Maitland J, Boyer R, Gallagher D, Duncan S, Bauer N, Kauser J, and Eifert J. Tracking cross-contamination transfer dynamics at a mock retail deli market using GloGerm™. *Journal of Food Protection*. Volume 76, Issue 2, pages 272-282, January 2013. (Bacterial cross-contamination in the deli)

Pan Y, Breidt Jr F, and Kathariou S. Resistance of *Listeria monocytogenes* biofilms to sanitizing agents in a simulated food processing environment. *Applied Environmental Microbiology*. Volume 72, Issue 12, pages 7711-7717, December 2006. (sanitation practices for Lm control)

Pennsylvania State University, College of Agricultural Sciences, Agricultural Research and Cooperative Extension. Control of *Listeria monocytogenes* in Retail Establishments. <http://pubs.cas.psu.edu/freepubs/pdfs/uk137.pdf>
(Guidance for Lm control)

Pennsylvania State University, College of Agricultural Sciences, Agricultural Research and Cooperative Extension. Control of *Listeria monocytogenes* in Small Meat and Poultry Establishments. <http://extension.psu.edu/food/safety/other-topics/controlling-listeria/Cotrolling-Listeria-2.pdf/view>
(Sampling for Lm, rotating sanitizers).

Pradhan AK, Ivanek R, Gröhn YT, Bukowski R, Wiedmann M. Comparison of public health impact of *Listeria monocytogenes* product-to-product and environment-to-product contamination of deli meats at retail. *Journal of Food Protection*, Volume 74, Issue 11, pages 1860-1868, November 2011 (Bacterial cross-contamination in the deli)

Pradhan AK, Ivanek R, Gröhn YT, Bukowski R, Sofos JN, and Wiedmann M. Quantitative risk assessment of listeriosis-associated deaths due to *Listeria monocytogenes* contamination of deli meats originating from manufacture and retail. *Journal of Food Protection*, Volume 73, Issue 4, pages 620-630, April 2010 (Cornell University comparative Lm risk assessment)

Ryser T and Marth EH (eds). 1999. *Listeria, Listeriosis, and Food Safety*. Second Edition (Lm and listeriosis overview)

Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, and Griffin PM. Foodborne illness acquired in the United States—major pathogens. *Emerging Infectious Diseases*, Volume 17, Number 1, pages 7-15, January 2011. (Estimates of foodborne illness in the U.S.)

Tompkin, RB. Control of *Listeria monocytogenes* in the food-processing environment. *Journal of Food Protection*, Volume 65, Issue 4, pages 709-725, April 2002. (Lm niche and sanitation practices)

USDA/FDA, Interagency Risk Assessment: *Listeria monocytogenes* in Retail Delicatessens, 2013. United States Department of Agriculture, Food Safety and Inspection Service and U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition. <http://www.fsis.usda.gov/wps/wcm/connect/c0c6dfbc-ad83-47c1-bcb8-8db6583f762b/Lm-Retail-Technical-Report.pdf?MOD=AJPERES>
(Lm risk assessment)

Vorst K L, Todd EC, and Ryser ET. Transfer of *Listeria monocytogenes* during mechanical slicing of turkey breast, bologna, and salami. *Journal of Food Protection*, Volume 69, Issue 3, pages 619–626, March 2006 (Lm cross-contamination from slicers)

Walker S J, Archer P, and Banks JG. Growth of *Listeria monocytogenes* at refrigeration temperatures. *Journal of Applied Bacteriology*. Volume 68, Issue 2, pages 157–162, February 1990. (Temperature and general background information)

1998 Food Safety Vine

Vertically Integrated National Enterprise

An AFDO Vision

Note from AFDO President, Joseph Corby: The Association continues to promote our vision of a vertically integrated national food safety system (Food Safety/VINE) at seminars and workshops and on the national level. The vision statement and schematic drawings included in this Journal were developed by past president Dan Smyly, Executive Director, Betsy Woodward, and myself. We look forward to your support and recommendations for improving this material and keeping AFDO in the forefront of this national effort. It is time we all get involved.

Today's food safety regulatory structure is a system that consists of multiple government oversight of the food industry and the foods they produce, distribute, and sell. This system, with an infrastructure that includes federal, state, and local government as participants, has served the public extremely well; we proudly boast to have the safest food supply in the world. While the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) are viewed as the major food safety regulatory agencies in the United States, it is state and local government programs that conduct more than 80% of the food establishment inspections, investigate the majority of foodborne illnesses, and sample the majority of food products for bacteriological or chemical defects. This is an enormous task and responsibility.

To ensure the public a safe, wholesome, and properly represented food supply, an effective food safety system must be a combined effort of the food industry, the government (at all levels), and the consumer. Surveillance research, risk assessment, effective regulations with science-based standards, appropriate inspection, enforcement and compliance activities, training, and education must be the cornerstones of any future food safety system. If there is a system breakdown resulting in foodborne illness, the industry must have the willingness and government must have the flexibility and the capacity to move swiftly to determine the cause of the illness, remove the implicated product from the marketplace, and build in strategies to prevent future recurrences.

Does such a system need to be invented? No. This system is already in place today. *Is the system perfect?* No. But over the years, it has continually improved; it has allowed the development of one of the safest—if not the safest—most abundant, most diverse, and most convenient food supplies in the world.

Can our current food system be improved? Absolutely. But the Association of Food and Drug Officials (AFDO) believes that we do not need to start over from ground zero—we need to determine more effective ways to enhance the synergism and strengthen the effectiveness of the federal, state, and local infrastructure currently in place.

When President Clinton announced the Food Safety Initiative to this country, much was said about the role of the federal government to assure the consuming public safe and wholesome food. Originally there was little said about state and local food safety efforts, despite the mammoth amount of work that had been done there and the

availability of abundant resources. As a result, AFDO decided to mobilize with their affiliates and state partners and proclaim that no real debate about a national food safety system could exist without including state and local jurisdictions. AFDO has spoken at conferences, seminars, and training workshops where they remind everyone about the enormous resources available in state and local programs. Recently a vision by AFDO was developed, detailing their views as to what a national food safety system could and should be. We call the system VINE (Vertically Integrated National Enterprise). We use the acronym VINE as a handy way of describing a joint effort of federal, state, and local food safety organizations. AFDO is aggressively promoting and articulating Food Safety VINE and the impact we believe it can have on improvement to and resource maximization for food safety in this country.

There are two key words within the acronym VINE: **vertically** and **integrated**. A **vertical** system is one which functions from the top to the bottom. At the top of the system, we envision the federal government providing leadership through technical support, setting of standards, risk assessment, evaluation of programs, certification of field personnel, training, and additional funding where needed. We believe the role of the state and local governments would be to perform domestic inspections, investigations, and collecting of samples much in the same way they currently do. Furthermore, we believe it is the responsibility of the federal government to provide the proper regulatory oversight of imported foods at entry point levels. By allowing states and local government agencies to handle domestic food safety affairs, the federal government can increase its oversight of imported food, which in our view is desperately needed. State and local governments should also continue their licensing programs and strong enforcement activities as they see fit. The vision of a vertical system is really a vision of coordination and uniformity, resulting in the elimination of duplicative efforts as well as better utilization of all current dedicated food safety resources.

An **integrated** system is a vision of joining these resources into a unified organization. It would include centralizing all current and available data relating to food safety, such as specific information on animal health, foodborne illness, food establishment inspections, and sample analysis. AFDO also believes an integrated system would include tracking mechanisms for foodborne illnesses and food defects which can be monitored by all states and local jurisdictions electronically.

To AFDO, whether the food safety system is implemented by an independent single agency or by multiple agencies is not the key to improving our overall system. What is vitally important, however, is the need to take a new look at our food safety system and to fundamentally change from our current concept of a “federal system” and a “state/local system” to a fully integrated “national system.” As a prerequisite to accomplishing this task, the roles and responsibilities of each federal agency involved with various aspects of food safety, as well as the roles and responsibilities at the state and local levels, must be explicitly defined. Once these roles are clear at the federal level, the roles of the counterparts at the state and local levels will fall into place over time.

AFDO has chosen to use the word enterprise in its acronym because we believe this is a daring and comprehensive plan. We shall solicit input from all potential players in this strategy, including government, industry, and academia.

AFDO concurs with the National Academy of Sciences' "Committee to Ensure Safe Food from Production to Consumption" as they recommend in their 1998 report that:

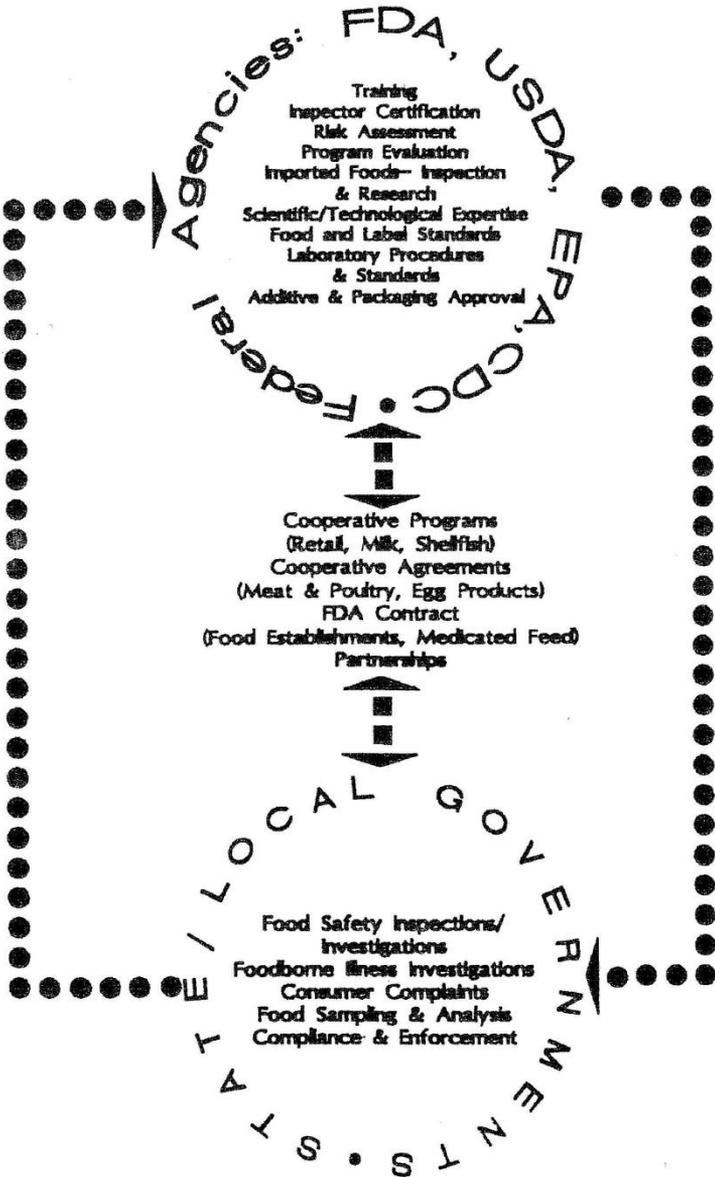
"The National Food Safety Plan should:

- include a unified, science-based food safety mission;
- integrate federal, state, and local food safety activities;
- allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;
- provide adequate and identifiable support for research and surveillance to:
 - monitor changes in risk or potential hazards brought on by changes in the food supply or consumption patterns; and
 - improve the capability to predict and avoid new hazards;
- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne disease and related hazards;
- address the additional and distinctive efforts required to ensure the safety of imported foods;
- recognize and provide support for the burdens imposed on state and local authorities that have primary front-line responsibility for the regulation of food service establishments; and
- address consumers' behavior related to safe food handling practices."

The dwindling resources available for government services mandate that government at all levels develop effective ways to work smarter and more cooperatively in the regulation of food. The states and federal agencies have a long history of working together through various cooperative agreements, contracts, grants, memoranda of understanding, and, most recently, partnerships. AFDO believes the time is right to get beyond partnerships and for all major stakeholders at the federal, state, industry, and consumer levels to work to develop a "blueprint" for the establishment of a truly vertically integrated national food regulatory system.

On the following pages are two schematics of VINEs. Each version depicts the relationship between all levels of government and their related functions.

FOOD SAFETY - VINE Tools



AN A.F.D.O. VISION

FOOD SAFETY -VINE Mechanisms



AN A.F.D.O. VISION

APHL Year 1 Progress Report
Building an Integrated Laboratory System to
Advance the Safety of Food and Animal Feed
EXECUTIVE SUMMARY OF YEAR ONE PROGRESS REPORT
September 10, 2012 – August 31, 2013

The Food Safety Modernization Act (FSMA), signed into law by President Barack Obama on January 4, 2011, provides the US Food and Drug Administration (FDA) with a framework to better protect public health by strengthening the food safety system. Its primary purpose is to ensure the safety of the US food supply by shifting focus to prevention of food and animal feed contamination through enhanced partnerships and integration among Federal, State, Local, Tribal and Territorial partners.

Since 2008, the Partnership for Food Protection (PFP) has been working across jurisdictions and across disciplines to develop an Integrated Food Safety System (IFSS). One way of achieving integration is the development of national standards. Accrediting food and animal feed laboratories to a recognized standard will ensure the rapid acceptance of laboratory data for compliance and regulatory actions.

The Association of Food and Drug Officials (AFDO), the Association of American Feed Control Officials (AAFCO), and the Association of Public Health Laboratories (APHL) continue to work towards meeting the goals of a five-year Cooperative Agreement with FDA to support food and feed testing laboratories seeking to achieve, maintain and enhance their accreditation to the ISO/IEC 17025:2005 standard. For the first year, 12 Association-led member groups worked on nine specific aims of this Cooperative Agreement. Workgroup involvement is voluntary yet very robust, with over 70 individuals actively contributing. Members are committed to the work and share a common goal of creating a unified food/feed laboratory system in the United States.

The following are some of the successes that these groups have helped APHL, AFDO and AAFCO achieve:

Hosting of a Food and Feed Laboratory Accreditation Discussion Board, an on-line forum for the exchange of information related to becoming accredited to the ISO/IEC 17025:2005 standard.

Creation of web pages to support Food and Animal Feed Testing Laboratories seeking Accreditation, including a repository of ISO/IEC 17025:2005 resources such as best practices, standard procedures, and work plans. As of October 8, 2013, 172 documents under 14 ISO categories have been posted.

Development of a Training Needs Assessment, a prioritized list of training topics, and a spreadsheet of currently available ISO/IEC 17025:2005 training. FDA and the Associations ensure effective coordination of training efforts to avoid duplication of effort. A pre-recorded webinar “ISO/IEC 17025 Road to Accreditation: Where to Start and What to Consider” was released in August 2013.

Delivery of three live webinars (two on Document Control Software, and one on Compliance Management Software) that demonstrated commercially available tools that may be of value to laboratories seeking accreditation to the ISO/IEC 17025:2005 standard.

Offering free registration for a webinar series on ISO/IEC 17025:2005 management requirements to all food and feed testing laboratories. Of 39 evaluations received, almost 100% of respondents agreed the 13 stated objectives were met; 95% agreed the material presented will help them perform their job better; 79% agreed they will recommend changes based on the information presented; and 95% agreed the course was worth the time spent to take it.

Development of a discovery report on data exchange among food and feed testing laboratories and FDA's eLEXNET. The discovery report is intended to identify gaps in the current landscape and suggest next steps to improve food and feed data exchange. Once FDA completes a final review, the discovery report will be posted on APHL's Food and Animal Feed Laboratory Accreditation website.

Expansion of a Subject Matter Expert (SME) Registry hosted on the AFDO website to include food and feed laboratory professionals. As of Sept 12, 2013, the registry includes 46 Food Laboratory SME's (100% increase since cooperative agreement was put in place). New categories of expertise include Pet Food Testing, Animal Feed Testing, Laboratory Accreditation, and Sampling.

Development of a curriculum framework (similar to the International Food Protection Training Institute Curriculum Framework for Regulatory Food Protection Professionals) to identify career-spanning training for food and feed laboratory professionals. Progress is being made on a curriculum framework diagram which depicts the professional development content areas that food and feed laboratory professionals should participate in over their careers.

Hosting the first Face-to-Face meeting of the ISO Awardees in Raleigh, NC. All 31 grantee laboratories attended and shared their experiences pertaining to ISO/IEC 17025:2005 accreditation.

Establishment of national standards for the collection and handling of food and feed materials as a critical component of ensuring equivalency of data from federal, state and local laboratories. A nationwide survey of state sampling personnel was conducted to determine issues with sampling processes. Additionally, state-based conference calls captured sampling needs and "spend a day with an inspector/sampler" visits captured day-to-day challenges. Work was initiated on a guidance document, GOODSamples (Guidance on Obtaining Defensible Samples).

Revision of the existing AAFCO Quality Assurance Quality Control Guidelines for State Feed Laboratories as a supplement to the ISO/IEC 17025:2005 Standard for feed laboratories. The guidelines will be released in February 2014 as three volumes and will include a copy of the ISO/IEC 17025:2005 standard.

Progress towards accreditation to the ISO/IEC 17043:2010 proficiency testing standard for the AAFCO Collaborative Check Sample Program (CCSP) and extension of the scope

of the CCSP to include pet food, heavy metal contaminants, mycotoxin contaminants, and veterinary drug residues.

Establishment of a Laboratory Directors Steering Committee to actively work with the Manufactured Food Regulatory Program Alliance (MFRPA) to address issues related to the Manufactured Food Regulatory Program Standard No. 10 (Laboratory Support). The Steering Committee will provide leadership on enhancing the program standards, implementing accreditation, improving integration, and promoting the standards and accreditation in jurisdictions where they have yet to be employed.

Development of a Clinical Isolate Submission report, outlining successful partnerships that improve clinical foodborne isolate submission to public health laboratories. The report describes ongoing challenges and proposes a pilot project to assist states in implementing successful programs. Once FDA completes a final review, the report will be posted on APHL's Food Safety Initiatives website.

Developing a Competency Framework for U.S. State Food and Feed Testing Laboratory Personnel

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A competency-based training curriculum framework for U.S. state food and feed testing laboratories personnel is being developed by the International Food Protection Training Institute (IFPTI) and three partners. The framework will help laboratories catalog existing training courses/modules, identify training gaps, inform training curricula, and create career- spanning professional development learning paths, ensuring consistent performance expectations and increasing confidence in shared test results. Ultimately, the framework will aid laboratories in meeting the requirements of ISO/IEC 17025 (2005) international accreditation and the U.S. Food Safety Modernization Act (U.S. Public Law 111-353). In collaboration with the Association of Food and Drug Officials, the Association of Public Health Laboratories, and the Association of American Feed Control Officials, IFPTI is carrying out the project in two phases. In 2013, an expert panel of seven subject matter experts developed competency and curriculum frameworks for five professional levels (entry, mid-level, expert, supervisor/manager, and senior administration) across four competency domains (technical, communication, programmatic, and leadership) including approximately 80 competencies. In 2014 the expert panel will elicit feedback from peers and finalize the framework

The International Food Protection Training Institute (IFPTI), in collaboration with the Association of Food and Drug Officials (AFDO), the Association of Public Health Laboratories (APHL), and the Association of American Feed

Control Officials (AAFCO), has been developing a competency- based curriculum framework in 2013–2014 that will help aid the U.S. system of regulatory public health laboratories in meeting the requirements of ISO/IEC 17025 (2005) international accreditation and the U.S. Food Safety Modernization Act (FSMA; 1). The project, which is funded by a cooperative agreement with the U.S. Food and Drug Administration (FDA), will help laboratories catalog existing training courses/modules, identify training gaps, inform training curricula, and create career- spanning professional development

learning paths, thus ensuring consistent performance expectations and increasing confidence in shared test results.

The U.S. system of regulatory public health laboratories includes state public health laboratories, local laboratories, state agricultural or environmental agency laboratories, laboratories under a state chemist, and subsidiary laboratories that test food and/or feed. This system of laboratories protects the public against diseases and health hazards through clinical diagnostic tests, disease surveillance, and food, feed, environmental, and radiological analytical testing (2). However, as of 2013 not all of these laboratories were accredited under the only internationally- recognized laboratory accreditation ISO/IEC 17025 (2005) of the International Organization for Standardization/International Electrotechnical Commission (3). Prior to the initial publication of ISO/IEC 17025 in 1999, there existed only widely differing national standards for accreditation. ISO/IEC 17025 (2005) sets forth quality management systems documentation and implementation requirements for testing and calibration laboratories. Obtaining accreditation to this ISO standard will help establish equivalency among food and feed laboratories at all levels (local, state, federal, and private), thus enabling them to share test results with confidence that the findings are accurate and comparable.

The curriculum framework will also help laboratories meet the standardization requirement of FSMA, the most comprehensive food safety legislation enacted in the United States in more than 70 years. Section 202 of FSMA calls for the development of model standards that laboratories must meet in order to be accredited by a recognized accreditation body. These standards must address sampling techniques, analytical procedures, internal quality assurance, complaint response, employee qualification, and other criteria.

To obtain ISO accreditation and meet FSMA standards, laboratory professionals must have appropriate training and competency. Determining the scope and content of this training is the driving force behind Phase One—the development of a competency framework that describes the job competencies required by laboratory personnel. In Phase Two, the competency framework will guide the development of a training curriculum that will help identify training content areas, catalog existing training courses and modules, find gaps in existing training, and create new training to address those gaps. The curriculum framework will also allow food and feed laboratory professionals to identify gaps in their own professional development and allow those individuals to create personal learning paths.

The competency-based training curriculum framework will be similar in concept to that created by IFPTI in 2012 for regulatory food protection professionals working at the federal, state, local, tribal, and territorial levels, at the request of and in collaboration with the FDA (4). The IFPTI framework is supported by the FDA, the World Bank, and other food and agriculture institutions and agencies. For example, IFPTI has had meetings with the Canadian Food Inspection Agency regarding implications and possible implementation of a similar framework for Canada.

Method

The development of the competency framework used a back mapping design process to plan results-based professional development (5). The process identifies desired training

outcomes and designs a system to achieve those outcomes. IFPTI, AFDO, APHL, and AAFCO began Phase One by convening an expert panel of seven food and feed laboratory subject matter experts with an appropriate range and depth of knowledge, skills, and experience in state food and feed testing laboratories. The panel met on August 21–22, 2013 at the Kendall Center of Western Michigan University, adjacent to the IFPTI headquarters in Battle Creek, MI. The meeting was led by IFPTI, and the panel included (in alphabetical order):

Maria Ishida, Bureau Chief, Florida Department of Agriculture and Consumer Services, Division of Food Safety, Bureau of Food Laboratories;

Ron Klein, retired, former manager of the Alaska Food Safety and Sanitation Program, and AFDO Program Director;

Susan Murphy, Quality Assurance/Safety/Training Manager, Biosafety Officer, Virginia Division of Consolidated Laboratory Services;

Daniel Rice, Director, New York State Department of Agriculture & Markets, New York State Food Laboratory;

Yvonne Salfinger, retired, former Bureau Chief and AFDO Program Consultant, Bureau of Food Laboratories, Division of Food Safety, Florida Department of Agriculture and Consumer Services;

Steve Sobek, Director, Bureau of Laboratory Services, Wisconsin Department of Agriculture, Trade and Consumer Protection;

Kathleen Wickman, Laboratory Manager, Oregon Department of Agriculture.

The first step in Phase One defined the target audience. The panel defined the primary audience as state regulatory (public) food and feed testing laboratory professionals, although the audience could also include laboratory professionals working in the private sector. The term “food and feed laboratory professionals” was defined to include laboratory technicians, chemists, and microbiologists, but not administrative/support staff such as security officers, custodial personnel, secretarial staff, grounds-keeping personnel, and information technology staff (individuals who fix computers, load software, or set up networks for the laboratory as opposed to database managers and professionals responsible for Laboratory Information Management Systems).

Results

The second step in Phase One drafted a competency framework, which is a model that broadly defines the blueprint for excellent performance within an organization, sector, or profession. The competency framework helps identify desired outcomes or behavior, enumerates metrics by which competency can be measured, spells out observable and measurable characteristics, and provides evaluation criteria, e.g., “A food or feed laboratory professional at the entry level has achieved a technical competency if he or she can explain laboratory testing methods and perform laboratory tests independently and correctly.” The second step included two initial tasks: identifying professional levels and identifying specific types of competency domains.

The panel identified a total of five professional levels, along with preliminary definitions for each level:

(1) *Entry level.*—Newly hired laboratory professionals who have been on the job for up to approximately 2 years and who have a limited testing scope and complexity.

(2) *Mid-level.*—Laboratory professionals with a more expanded and increased testing scope and complexity.

(3) *Expert level.*—Laboratory professionals with more than 5 years of experience who have an extensive range of testing scope, a high level of knowledge on testing principles, and the ability to independently perform problem-solving tasks.

(4) *Supervisor/manager level.*—Laboratory professionals who have laboratory skills, can manage laboratory workload and supervise entry, mid-level, and expert levels.

(5) *Senior administration level.*—Laboratory professionals who have laboratory, management, and leadership skills to oversee all administrative management duties for the laboratory. Next, the panel identified and defined four types of competency domains that apply to each professional level:

(1) *Technical competency.*—The ability to perform tasks related to certain subject matter (e.g., chemistry, microbiology).

(2) *Communication competency.*—The ability to effectively and appropriately interact with others to achieve desired goals.

(3) *Programmatic competency.*—The ability to guide technical functions to accomplish the organizational mission.

(4) *Leadership competency.*—The skills and behaviors that contribute to superior performance.

The professional levels, along with the four domains, were then mapped onto a framework.

The panel then identified the technical, communication, programmatic, and leadership competencies necessary for each level of employee, beginning with the entry level and working up to the senior administration level. The competencies were placed in the appropriate cell in the competency framework as shown in Table 1.

Table 1. Proficiency levels and mapping competencies onto the framework

Proficiency levels/domains	Technical competency	Communication competency	Programmatic competency ^a	Leadership competency
Senior Administration				Advocate for resources. Establish organizational culture. Lead strategic planning efforts.
Supervisor/Manager				
Expert				
Mid-Level		Present ideas clearly to his/her peers. Write SOPs. Create data summary reports.		
Entry Level	Explain laboratory testing methods. Perform laboratory tests independently and correctly.			

^a The expert panel determined that the same programmatic competencies would apply to both Entry Level and Mid-Level food and feed laboratory professionals.

For example, in order to demonstrate technical competency, an entry level laboratory professional should be able to explain laboratory testing methods and perform laboratory tests independently and correctly. In order to demonstrate competence in communication, a mid-level laboratory professional should be able to present ideas clearly to peers, write standard operating procedures, and create data summary reports. In order to demonstrate competence in leadership, a senior administration level laboratory professional should be able to advocate for resources, establish organizational culture, and lead strategic planning efforts. Competencies within a given domain are cumulative, which means that the competencies at one level build on the competencies of the previous level(s). Thus, a mid-level professional should have the competencies of an entry level professional and be working to acquire the competencies expected of a mid-level professional.

The panel initially identified more than 80 specific competencies and applied the competencies to the appropriate professional level and competency domain. Tables 2–5 represent the complete competency frameworks drafted by the group for the five proficiency levels/domains, beginning at the highest level (senior administration) and ending with the lowest level (entry level).

Table 2. Draft competency framework: senior administration level

Technical competency	Communication competency	Programmatic competency	Leadership competency
Anticipate and evaluate resource needs.	Distill complex technical information for a variety of audiences. Interact with media organizations regarding sensitive issues. Disseminate the vision, mission, goals, and objectives throughout the organization.	Strategically prioritize and allocate resources. Collaborate in the development of new program standards. Create or modify policy. Establish fee structures. Oversee facility management.	Advocate for resources. Establish organizational culture. Lead strategic planning efforts. Promote an integrated food safety system.

Table 3. Draft competency framework: supervisor/manager level

Technical competency	Communication competency	Programmatic competency	Leadership competency
Assess work performed by experts. Determine if experts' conclusions are valid. Interpret a compilation of test results and explain the implications.	Interact with media organizations regarding non-sensitive issues. Write concise business reports. Conduct conflict resolution and negotiation. Provide clear instructions to experts. Inform senior administration of challenges, opportunities, resource needs, etc. Effectively disseminate information. Produce effective written and oral interpersonal communications.	Assess program performance using data. Suggest new methods. Interpret and apply emerging technologies. Implement new policies. Ensure compliance with work rules, policies, and practices. Employ program standards relevant to the laboratory. Administer accreditation or certification standards that pertain to the administrative operations.	Motivate laboratory professionals. Implement the strategic plan. Advocate for laboratory staff members. Engage in interagency collaboration. Engage in integrated food safety system activities.

Table 4. Draft competency framework: expert level

Technical competency	Communication competency	Programmatic competency	Leadership competency
Troubleshoot problems. Train laboratory professionals. Interpret and describe standard and nonstandard test results. Evaluate data using statistical modeling. Evaluate and implement technologies. Conceptualize and develop novel approaches.	Engage in public speaking. Write for publications. Independently interact with peers regarding technical information. Participate in workgroups and professional organizations. Build collaborations. Write technical reports or documents. Facilitate meetings.	Collaborate on applicable grant opportunities. Apply regulatory standards in assessing data and reporting results. Administer accreditation or certification standards that pertain to the laboratory testing operations.	Participate in strategic planning. Mentor laboratory professionals. Demonstrate professional laboratory behavior. Contribute to professional field.

Table 5. Draft competency framework: mid-level and entry level

	Technical competency	Communication competency	Programmatic competency	Leadership competency
Mid-Level	<p>Apply testing knowledge and skills to similar testing methods.</p> <p>Apply knowledge and skills to use similar technologies.</p> <p>Participate in trouble-shooting problems.</p> <p>Describe results in terms of work performed.</p>	<p>Present ideas clearly to peers.</p> <p>Write SOPs.</p> <p>Write in a grammatically-correct style.</p> <p>Create data summary reports.</p> <p>Write corrective action reports.</p> <p>Articulate issues.</p> <p>Present information about work performed as evidence in legal proceedings.</p>	<p>Describe regulatory programs that the laboratory supports.</p> <p>Explain roles and responsibilities in the quality system.</p> <p>Articulate roles and responsibilities in a safety program.</p> <p>Explain the roles and responsibilities of personnel and programs within their laboratory.</p>	<p>Initiate problem resolution.</p> <p>Recommend innovative solutions.</p> <p>Recognize and proactively address issues and gaps.</p>
Entry Level	<p>Explain laboratory testing methods.</p> <p>Perform laboratory tests independently and correctly.</p>	<p>Clearly record observations.</p> <p>Follow written and verbal directions.</p> <p>Seek assistance or clarification when necessary.</p> <p>Discuss laboratory-related issues clearly, logically, and succinctly.</p>		<p>Consistently behave in ethical manner.</p> <p>Pursue professional growth.</p> <p>Assume responsibility and accountability for actions.</p>

The panel then began the process of validating all the competencies identified during their August 2013 meeting. This validation involves identifying existing competencies from other sources and/or vetting the competency framework with state food and feed testing laboratory peers and colleagues. The group will then map any new additional competencies onto the competency framework and revise the draft competencies as shown above.

Discussion

The IFPTI competency-based training curriculum project is creating an evidence-based, national framework of professional laboratory personnel competencies in conjunction with a national training curriculum framework. The project provides a major, essential tool for all U.S. state food and feed testing laboratories that seek to gain ISO/IEC 17025 (2005) international accreditation and to meet the regulatory requirements of FSMA.

A substantial part of this project's success in meeting FDA Cooperative Agreement requirements and partner expectations is that it builds directly on the national curriculum framework for public regulators, an IFPTI-led activity from 2011–2012. That framework has been approved not only by the FDA, but also by the World Bank and foreign governments.

From the AFDO Archives (1941)

Sausage Meats

**J.W. Forbes, Director Bureau of Foods and Drugs, Montana
Presented at the Forty-fourth Annual Conference at New Orleans, La.,
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There is a need in talking of sausage meats to differentiate.

1. Ground fresh meats—
 - Hamburger
 - Pork Sausage
 - Country style sausage
2. Prepared sausage meats—
 - Wieners
 - Frankfurters
 - Bologna
 - Etc.

Also there is need to establish the fact that there is no definite standard for these types of products. Meat men since time immemorial have had their own way, putting anything in these, comminuted or ground meats.

In the problem of regulating meats and meat products the states at the present time are very largely guided by the Bureau of Animal Industry regulations. Consider, however, that the Bureau of Animal Industry regulations presuppose an ideal condition, where plant procedures and operations are under continuous supervision and control. All ingredients coming into the plant, whether animals for slaughter, flour, milk powder, spices or otherwise, are subject to inspection for quality and must meet certain very rigid requirements.

Contrast to that the almost entire lack of ingredient control in plants not under the Bureau of Animal Industry, not only of animals for slaughter but of other ingredients. The Bureau of Animal Industry inspector can sample any product at any time and, if suspicious, withhold use or sale until analyses have been made and laboratory tests show the product to be satisfactory or not. Whereas in uninspected plants, almost any type of animal or grade of other ingredient can be and frequently is used. In the inspected plant, only approved materials may enter the plant. In the uninspected plant, any kind of adulterant may be brought in and used for considerable lengths of time before being found, depending on efficiency of the inspection service and analytical staff.

The sale of fresh meats is to a very great extent a local problem and should be faced as such. Under the Federal Food and Drug Administration, as well as the Bureau of Animal Industry regulations, hamburger is defined as ground beef with or without suet or seasoning. Pork sausage is defined as ground or chopped pork, with or without various seasoning products such as herbs, spices, salt, sugar, dextrose, syrup, and water.

These are more or less standards of exclusion. Anything not mentioned should not be added. This leaves out cereal flours, dry milk powder, potato flour, soybean meal, crackers, bread crumbs, or coloring agents such as tomato juice or paprika. Yet any or all of these might be present at one time or another in local products.

No attempt is made to place a limit on fat content. In Montana at least, it is common practice to use for hamburger, bulls or canner cows plus such scraps or trimmings as might accumulate during operation. Such meat contains as a rule less than 10% fat and sometimes as low as 2%. In the instance of one chain store, they were buying trimmed bull meat at 11 cents per pound, grinding it up with sufficient fat to raise the fat content to over 28%, and selling it at 2 pounds for 19 cents. By calculating the difference between selling price and cost, they were getting almost 15 cents per pound for the fat they had added.

This addition of fat beyond a reasonable amount is an adulteration just as much as the addition of flour and water. Some hamburger has been found to contain as much as 40% fat. On analysis of several hundred hamburger samples in a blanket sampling of the state, it was found fat content ranged from 2% to 40%, with the average around 16%. After some consideration, it was felt that as a whole, 20% fat in hamburger should be fair standard. Opinions from a number of states' officials seemed to regard this as a reasonable figure. Meat men throughout the State were also contacted. A great many concurred in the fairness of the 20% fat standard. Some felt it should be 25%. However, I believe there should be a limit, and knowing meat men and their practices, I still believe the 20% fat limit for hamburger is reasonable.

With pork sausage, you have a somewhat different picture. Pork is from a much fatter animal, although the butcher in buying pork pays less for a very heavy animal than he does for one of reasonable weight. When it comes to cutting the hog to prepare for sale over the block, the meat man trims off quite large amounts of fat, which very evidently he considers excess fat, or it would be left on the animal to be sold to the housewife, the same as heads and feet of poultry. If the housewife still thinks the meat too fat, the butcher will trim off additional slices of fat.

When the heavy layers of fat, which very evidently both the butcher and the housewife consider excessive, are trimmed off, there is by no means 50% fat or even 40% fat left. The only chunks of port sold containing 40% or 50% fat are the bacons, salt pork, or fresh side pork. In any case, the housewife sees and knows what she is buying and if too fat, refuses to buy.

She has no opportunity to see how much fat she is buying when she gets sausage. In my opinion, it is just as much an adulteration for the butcher to grind up all the fat of the hog in making sausage to put out a product of 50% to 60% fat as to add cereal or other adulterants. In other words, if it is excess fat over the block, it is excess fat through the grinder.

Our work in Montana has shown the fat content of sausage to vary from 15% to 65%, with the average about 36%. It was our opinion that 40% fat was a more than liberal

limit to set, and this has been confirmed by a number of State officials and by the meat men themselves.

One quite common adulteration of sausage is the grinding of a mixture of veal trimmings with pork fat, which when seasoned simulates very much an all-pork sausage. When the price of veal is low and pork is high, this is a very easy way to “gyp” the public. Even if veal is more expensive than pork, it makes the butcher money since the fat brings much larger returns at 25 to 30 cents a pound in sausage than it does at 7 to 8 cents per pound in lard.

Use of pork as an adulterant of hamburger is especially reprehensible because of the possibility of trichinosis infection. Many people prefer their hamburger rare, so there is considerable danger if pork is added to the ground beef and the mixture not thoroughly cooked.

There is also the matter of permitting the addition of chopped ice or ice water in pork sausage in amounts not to exceed 3%. We fail to see the need or reason for permitting such an adulteration. The argument is advanced that the grinder heats up and in turn heats the meat, which is prevented by the adulteration. If this is true it seems as though we should require a water or ice cooled grinder. Other types of adulteration have been eliminated by improved machinery; why not this?

Prepared sausage meats present a different picture. Trade custom over years past has established the use of cereal and water in manufacturing these various sausage products. At one time the Bureau of Animal Industry regulations limited the manufacturer to 2% added cereal and sufficient water to facilitate grinding and stuffing.

Some few years ago this was raised to 3.5% cereal, expanded to include dry milk powder and a limit set of 10% added water in the finished product. Meat men claimed need of cereal as a binder, although the best products contained none. In fact the only reason for using it is to cheapen the product.

Milk powder is a definite meat substitute, since it runs 35% more or less of protein. Its addition further complicates the analytical work connected with checking these sausage products.

No doubt the Bureau of Animal Industry had some reason for increasing the use of added adulterants in these sausage products. On my part, I fail to see the rhyme or reason for such liberality. Meat contains a certain amount of natural moisture; add a dry flour or milk product and it absorbs some of this natural moisture so that added water is needed to permit working the product for stuffing in casings. Naturally the more dry ingredients you add the more water you need, so you set up a vicious cycle of add more flour, add more water.

The question is raised that the poor people can buy more sausage at the reduced prices under which the adulterated products are sold. This is to me very funny. The added cereal or milk powder costs the sausage maker seven or eight cents, the added water nothing, so to speak. It would be much better if the poor people could get all meat for

their money at 20 to 25 cents per pound and buy their own flour at 7 or 8 cents per pound, and get their own water free of charge.

It would probably be impossible or at best extremely difficult to eliminate this particular type of adulteration as a source of revenue for the sausage maker due to the well-established trade custom. They make a number of other sausage products, as well as meat loaves of one sort or another, in which they do not incorporate any of these dry ingredients. It seems reasonable to me, therefore, that the use of these dry ingredients could be reduced or eliminated with a resulting decrease in the amount of permitted added moisture. If the addition of 3.5% of cereal or dry milk powder requires 8% to 10% added moisture to make a palatable product, is it not reasonable to assume that by eliminating the 3.5% of dry ingredients, the added moisture could be reduced at least by half? If that were done, the consumer would be paying sausage prices for only 5% adulterants as against 13.5% as at present.

It has been expressed to me that at such time as the majority of States indicate their desire for a downward revision with regard to permitted use of added adulterants, the Bureau of Animal Industry will take steps to consider the matter. I should like to recommend, therefore, that this organization extend to the Bureau of Animal Industry the request that they take such action as may be necessary to reduce or eliminate the addition of dry adulterants in prepared meat products with a resultant reduction in the amount of permitted added moisture.

I should also like to recommend to the various States that you carry on investigational work within your various State departments to see whether or not you get the same results in regard to your ground fresh meats as we have determined in Montana. Should you find similar conditions existing within your various jurisdictions, it might well be a matter for further consideration at future meetings to draw up uniform standards for submission to the various State regulating agencies and the Bureau of Animal Industry.

We have been using a rapid method in Montana for determining the amount of fat present in meat products. The A.O.A.C. method uses two grams of the sample. We found it almost impossible to get check results using only two grams but have obtained very satisfactory checks with a 10 gram portion of the sample. The 10 grams of ground meat or meat product is weighed into a tared dish and dried overnight or to constant weight in a drying oven at the temperature of boiling water. The loss in weight is recorded as moisture by drying. The fat is extracted from the residue with 3 or 4 portions of ether or high test gasoline. A hardwood pestle is used to break up the large chunks of dry material and allow intimate contact with the solvent. The dish is again placed in the oven to drive off the solvent and the loss of weight recorded as fat.

We will welcome criticism of this method, but I must say we have had excellent checks with this procedure.

The Changing Food Supply
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Presented at the Forty-fifth Annual Conference, St. Paul, Minnesota, June
1941

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The title embraces too much. We have fairly dependable data on agricultural production, rate of growth of population, trade, and industrialism in the Western Hemisphere, in Europe west of Russia, in South Africa, and in Australia. We have much less information on Russia; for the rest of the world, we have no information good enough to use in forecast. Therefore, we deal with the Western world outside of Russia, in an appraisal of "The Changing Food Supply," and our best information bears on the United States. The title implies that the food supply changes significantly from one date of reference to another; and this is true, whether considered from the standpoint of nutrition or of economic goods and services. If one will contrast the censuses of agriculture in 1900 with those of 1940, the difference in data is found to be extraordinary. It is important to appreciate to what an extent, before the twentieth century, qualitative information exceeded quantitative information; there is a large but scattered literature on diets at different times, in different countries and in different classes and ages. Knowing physiological requirements, from such books we are able to reconstruct rough guesses of the quantitative food supply.

The first comprehensive estimate of the food supply of a people appeared in Germany in 1915 in the Report of the Eltzebacher Commission, soon followed by the survey of food supply in the United Kingdom, by T. B. Wood. Then appeared, as collective reports of the Inter-Allied Scientific Commission on Nutrition, estimates of the food supplies of the United Kingdom, France, and Italy, as well as requirements of the animal feeds. In 1920 appeared the survey of our pre-war food supply by Pearl under the title **The Nation's Food**. The Germans have prepared new estimates in the '30s, and a new estimate lies at the basis of the British rationing system in the present war. In this country an admirable compilation of figures, without text, was issued by the United States Department of Agriculture for 1939. Few countries have censuses of food supply except under the pressure of war. Wars promote statistics. Once prepared, such estimates furnish the basis for regular revision and improvement.

A food supply is to be judged by quantities, qualities, and prices. Certain adjustments ought to be attempted. Carry-overs of processed foodstuffs, as well as of crops, are important variables. Variations in inventories are particularly important in the understanding of price changes. Recent refinements in estimates include more accurate separation of raw from processed food products, with some attempt to evaluate relative proportions of commercial and domestic processing.

- I. The first step in a correct appraisal of the food supply is a rejection of the sociological doctrine of Malthus that population inherently presses on food supply – and instead to accept the technological fact that for the Western world (and in particular in the United States), food supply presses on

population. It is not supply which must be increased to meet demand; demand which must be supported to absorb supplies. Supply and consumption are the two sides of the same thing.

The second point to be emphasized is not only expansion in total supply, but extraordinary diversification in different foodstuffs and in methods of processing and distribution. The available total supply is abundant beyond needs (of which we have had varying degrees of gluts in agricultural products ever since the World War), also the varieties available to consumers' choice and the diversification in processing and distribution present an almost bewildering display. Emphasis needs to be laid on the major fact that what is going on in the changing diet is not only increase in total amount, but also advance in specialized demands based on nutritional requirements—together with developments in purchasing power—to satisfy need for specialties in the physiological and psychological sense as well as need for staples in the sense of nutrition of domesticated animals. The major changes in our food use since the war are increases in fruits and vegetables (outside of apples and potatoes), increase also in dairy products, small decline in meats, and heavy decline in cereals.

In the original report of Pearl, in the German report, and in the reports of the food supplies of the United Kingdom, France, and Italy—prepared during war—attempts were made to measure quantities of protein, fat, and carbohydrate, together with calories involved, which enabled statisticians (with the use of figures for populations) to determine per capital intake per day. A further refinement consisted in conversion of total population into "average adult males"—rather an imposing elaboration, but one of obviously lessening import as calories decline. So far as I am aware, no one has attempted to compute the quantities of vitamins or minerals in the food supply, though this could be done in selected regions, just as it has been done for selected population groups.

- II. The food of a population in a crop year is the equation of supply with demand in price. The average annual ingestion of food is stated on assumption that all foodstuffs are available to all consumers, with equal freedom of selection and purchase. This, however, could not occur unless the cost of living were very low contrasted with income, and food habits and ideas on nutrition were diffused into accepted standards. In the United States, we have the highest concentration of factors influencing a food supply. Here those demands which are elastic are more elastic than in other countries; thus the range of choice and substitution is wider than in Europe. We have in this country fewer ritualistic influences, rare vestiges of superstition, less folklore of custom and tradition—the attitude of mind toward the food supply is more open and experimental.

Perhaps the most misleading inference applied to a changing food supply is based upon the abuse of the average, the arithmetical mean. For each individual or family, such and such amounts of foodstuffs are available, but of course it does not follow that they purchase them. It is, therefore, necessary to consider the diet from the standpoint of income groups in the population. In the upper income groups, let us say above 5 thousand dollars per annum per family, changes in prices of particular foodstuffs,

irrespective of qualities or of amounts available, have little effect upon food purchased; descending the scale of income, the more effective become price levels of foods and non-foods and position of real purchasing power of family income. This is an illustration of the rule of Engle. To an unfortunate extent, as has been shown the world over in innumerable studies, the family futilely attempts to protect itself by taking the lowest-priced foodstuffs, irrespective of nutritional value. But illustrations are also easily adduced to indicate that need for food may be sacrificed to demand for less essential goods and services. The effects of frustrations and futile adaptations in low income classes are made worse by ignorance of nutritional values and by disruption of habits and customs, which in many ways contain older experiences of value.

If one takes such a book as **“The Englishman’s Food”** by Drummond, and reads it in connection with a history of prices and wages in England, one feels warranted to make the comment that most of the changes in diet portrayed by Drummond could have been inferred from the course of prices and wages. Whether a food supply is constant or changing, let us say for reasons of improvement in agriculture and in foreign trade, the broad fact remains that a limited portion of family income is expended for food; when wages and prices permit food expenditures to be increased to some extent (though often with pathetic exceptions), the food supply becomes improved. But with all respect for habits and customs, there is an element of do-without in the food supply of low-income families; and when income permits, substitution occurs upward, just as it occurs downward under increasing pressure of poverty.

- III. From the dynamic point of view, we divide foodstuffs nowadays into (a) caloric foodstuffs, (b) accessory foodstuffs, and (c) beverages, including a large group of alcoholic and non-alcoholic beverages. Up to the time of the World War, changes in the diet were measured on the caloric basis, by changes in the relative proportions of protein, carbohydrate, and fat. Since the World War, advances in scientific knowledge have brought realization of the importance of the “accessories,” including in the term the vitamins and minerals. This extraordinary advance in nutritional science is most strikingly exhibited by contrasting the rationing of military forces and non-combatants in the present war with that during the World War. The principle of rationing in belligerent and neutral countries in the present war represents, in a sense, an experiment in mass nutrition. It is rationing devoted to health in the widest sense—whereas only a quarter of a century ago, the ration meant little more than provision for body heat and muscular exertion. Put in another way, today the demands of metabolism of special tissues and functions all find expression in the allowances of vitamins and minerals in various foodstuffs—not to the exclusion of proteins, fats, and carbohydrates, but at least in the sense of equal importance.

From time immemorial, a more or less important fraction of the food supply has been derived from the high seas. In the qualitative sense, sea food is important in contribution of vitamins A and D. In the quantitative sense, it is important in contribution of oils and fats which, in substitution of other animal and vegetable oils and fats, has had significant effect upon the total fat intake and upon relative proportions of the different fats. Improvements in the technique of catching whales has practically revolutionized the production of butter-substitutes in

European countries since the World War. When we recall the extent to which oil-seeds in Europe furnish protein concentrates for dairy herds and fats as substitute for butter, and then suddenly observe the supply of fat heavily augmented by whale oil, the influence of these circumstances upon the diet of Europeans becomes understandable.

It is difficult to say which of the main directions of improvements in the field of foodstuffs since the World War has been most striking: expansion in knowledge and education in the science of nutrition; developments in production and processing of foodstuffs; or developments in transportation, communications, and distribution. In a certain sense, these overlap, and the improvements in the one field support those in the other fields and indeed make them possible. At the same time, these improvements do not advance at an even pace; therefore, in a particular decade, one factor may exert greater influence than the others upon the changing food supply. Among numerous factors some are obviously major, and others minor, factors. But a major factor of one decade may become a minor factor in another; and certainly they do not march forward at an even pace and are not consecutive, or even cumulative. Therefore, in a dated period it is sometimes difficult to say whether a particular factor is a major or minor factor. In considering the influences of various factors on the changing food supply, it is thus necessary to realize that direct and indirect effects may supplement each other, or oppose each other, and may indeed obscure each other.

- IV. The title would seem also to indicate that changes in the food supply are believed to be inherent in the disorder of the world, now and after the war. This is true in the broad sense. After the World War, changes in food supply occurred in most countries; after this war, further and perhaps greater changes may occur in many countries. What is important is not prediction of change, merely as post-war movement, but the attempt on technical and historical grounds to forecast directions in which these changes may be expected to proceed.

The per capita potential food production has been rising, while the rate of growth of population has been declining; also the per capita ingestion of the normal food supply in the Western world has been falling. The cumulative effect of these three inevitable trends explains why pressure of population on food supply has been replaced by pressure of food supply on population.

In all countries, farmers claim and retain a more than per capita share of domestic crops. The decline in work animals in a country has an influence upon the changing food supply. In the first place, the number of work animals has an effect upon the number of animals devoted to production of edible products. Secondly, the number of animals influences use of fertilizers in agriculture. Decline in work animals sets free acreage, whose disposition in outturn of foodstuffs introduces changes in quantities, qualities, and prices of foodstuffs. If we had now the per capita number of work animals which we possessed in 1900, our agriculture, and in consequence our food supply, would be significantly different from the present.

With each year (war aside), what might be called the per capita outlay of muscular work in occupations declines, while the per capita participation in leisure rises. This has, of course, an indirect effect upon the total food supply, since it implies a considerable reduction, in the course of a generation, in calories per day per capita. A related influence is to be seen in the decline in exposed out-of-doors occupations and in protection against cold through improved housing construction. Gradually in our population the proportion of food ingestion which is devoted to maintenance of body-heat in exposed occupations, to support of body heat indoors, and to muscular exertion declines, while the requirements for reproduction, growth, and metabolism remain the same. Thus with each decade, an increasing proportion of the requirement goes to tissue needs rather than to heat and manual work. In this country, the proportion of the diet going to support of manual work is smaller than in other Western countries, which means that elasticity of demand for foodstuffs for other needs than support of physical work is given freer scope. This modifies the use of food in public eating places as well as in homes.

- V. The technique of production, grading, storage, transportation, processing, substitution, and final distribution to consumers has been changing actively for twenty years and will continue to change. Agriculture in all Western countries will continue to progress from the stage reached through the developments of the past twenty years. Progressively the technologists develop new types and varieties of plants and animals—whereby the unit of outturn per worker and per area progressively increases. Foodstuffs can now be stored for practically unlimited periods of time. The technique of all processings are being further perfected, amplified, and extended. Substitution of dearer natural foods with cheaper natural foods, and of natural foods with synthetic replacements, will expand. The potential capacity for food production in the Western world will continue to expand, despite (war-time) temporary partial withdrawal of working hands from plant culture and animal husbandry. While production will languish in some areas because of distance, it will be reinforced in other regions because of proximity. The per capita caloric intake in the Western world (which has been falling for two decades) will rise temporarily in proportion to greater (war) demands on muscular work. At the same time the recognized importance of the so-called accessory substances will tend to be enforced, with the result that the deleterious effect of war on nutritional public-health will be less than during and after the World War, except possibly in isolated blockaded regions. The potential increase in outturn of foodstuffs—which represents the technical achievement of the '20s and '30s—will serve in the '40s as safeguard and security, alike for belligerents and neutrals. This does not imply that war no longer carries menace to nutritional public-health, quite the contrary; but it indicates that date of significant food shortage may be postponed and degree of shortage subsequently reached will be less pronounced than in the absence of modern improvements in technique.

The progressive application of technology to the food supply, which began with agriculture and transportation, has extended to processing, with which we include refrigeration. From the perfection of new and improved varieties, through

improvements in harvesting and grading, with bettered distribution and transportation, we have arrived at conservation of the inherent qualities of meats, fruits, and vegetables through retention first of color, form, texture, and flavor, and finally of nutritional components, especially vitamins and minerals. This is, in fact, in a large sense, the final stage of improvement in the art of processing of foodstuffs—the retention or restoration of the important dietary accessories. Vitamins A, D, and, E in the fat-soluble series, and the pro-vitamins which precede them, can now be retained in foodstuffs in which they are naturally incorporated. The plants and their seeds, especially the cereals, contain very important water-soluble vitamins, of which thiamin ranks first; it is now practicable to retain these in the commercial processing of cereals, milled products, fruits, and vegetables. The art of synthesis has so far succeeded in this field, that where the retention of natural vitamins is not practicable, the addition of synthetic vitamins is technologically feasible. In fact, over the entire field, we are approaching the stage in which the only element of doubt revolves about cost, rather than about technical practicability.

- VI. We must expect changes to evolve in the food supply of the Western world as the expression, more or less, of abandonment “comparative advantage” with intensification of “economic nationalism.” Technical advancements enable Western countries, more or less at will, to reduce dependence on imports. We learned first in the splurging '20s, and later in the depressed '30s, that even with efficient distribution between countries, the doctrine of “comparative advantage” failed to hold adherence, or guide production of foodstuffs. “Security,” or what politicians regard as security, supersedes price, even in the limited sphere in which price holds something of its earlier characteristics.

Before the World War, the Western countries engaged in international trade (and to a large extent also other countries) possessed stable currencies directly or indirectly based on gold, whereby prices in one country were readily convertible into prices in other countries. Broadly speaking, transfers of agricultural products in international exchange between countries were quite like transfers of domestic products between the forty-eight states of our country. The stability in exchange mechanism, between producer in one country and consumer in another country, had the effect both of facilitating distribution and of lowering cost, as represented in the spread between producer and consumer. Agricultural products as a class are more perishable than industrial raw materials and manufactures; therefore, fluidity in the field of exchange, stability of the media of exchange, and foreseeability (or insurability) of future prices contributed with particular gain to international trade in foodstuffs.

The World War destroyed this system of international exchange and introduced one of the semi-planning (containing often reprisal or favoritism), with the result that expenses of transfer were increased, spreads widened, uncertainty accentuated, and forecast reduced. If history is to repeat itself, following the conclusion of the present war, there will be still less order and more disorder in the trade between nations. Disorder in distribution will inevitably affect the food supply of countries on net-importing bases, but also the food supply of countries on net-exporting bases.

The Western world during and following the war will operate on barter rather than through monetary media. To a large extent during the '30', European countries, for one reason or another and in one way or another, "adjusted" imports to exports. This was not confined to Germany, which bartered goods eastward in order to draw materials from thence. The imports of even the freest-trading country in Europe, the United Kingdom, gradually shifted into a situation of semi-barter on Empire basis, with imports determined by exports with lessened reference to price.

The food supply will be subjected to profound changes through control of foreign exchange, rationing of imports and exports, and allocation of materials. In effect, there has been rationing of foodstuffs in Europe for ten years, because when foreign exchange is controlled and allotments of materials established, necessarily there is a rationing, even though there be no enforcement by ration cards. The rationing of food under modern circumstances is an integral part of planned economy and cannot be separated from other elements of such planned economy. Thus, it is easy enough to show in country after country that the planning of production, of imports, of exports, and of exchange control of foodstuffs and industrial raw materials, and manufactures of both, react upon each other. Under these circumstances, it is inevitable that production and processing of foods should be significantly modified, thus invoking changes in the food supply.

- VII. In most countries, to greater or lesser extent, various forms of direct and indirect taxation are placed on foodstuffs in the flow from primary producer to final consumer. These introduce disturbances into the otherwise position of comparative advantage, disturb consumers' choice as between food classes, and limit consumer purchasing power. Irrespective of consumers' customs and of nutritional doctrines, the imposition of excises, always more or less inequitable, is certain to operate in the direction of changing the food supply, and usually not to the good.

In most countries one or another form of direct or indirect subsidy to production of foodstuffs is in force, and these tend to multiply. Such subsidies tend, other things equal, to reduce consumers' prices in the domestic or foreign market, as the case may be. Conversely, subsidies to producers or particular foodstuffs have the effect of creating disadvantage to producers of unsubsidized foodstuffs, so that a relative lowering of price in one class may tend toward relative increase of price in another class. In most countries, there are pressure minorities within agriculture, just as within industries. Of course the final operations of subsidies tend again toward disturbance of otherwise comparative advantage.

- VIII. Finally we come to the effect of political relationships. Net-creditor importing and exporting states will have different policies than net-debtor importing and exporting states. Countries with colonial possessions—on the assumption that relationships survive the war—will more than ever favor imports from their own dependencies. Ownership of steamship lines will influence the direction of imports and exports.

The quasi-self-sufficient largest net-creditor country, the United States, will have to struggle against isolation. Paradoxically, deficient countries seem to plan their

economics more successfully than surplus countries. Political preferences will be set up against political aversions; a country like ours, which lacks preferences and aversions in foreign relations, may find itself injured on both sides and the gainer on neither.

All of these influences will come to pass within the food supply of the Western world and in our country for the simple reason that the food supply is merely one of the fabrics of material civilization. The time has passed when the food supply could be set apart and given an isolated attention and treatment, with secondary consideration of the other relations of life. Indeed, under the conditions of modern technique, the food supply may receive not the first attention in a planned economy, but rather a second attention—on the broad assumption that knowledge of nutrition and skill in processing, storing, and distribution will provide security in the domain of foodstuffs more than in the domain of essential raw materials and their manufacture.

- IX. The rate of growth of population will have significant effect upon a changing food supply, though what such effect may be will depend upon varying circumstances. We have today a population of about 131.5 million; it would be over 160 million if the rate of growth observed in the Census of 1890 had been continued. Other things equal, our diet with a population over 160 million would be different than it is today with a population of 131.5 million. The age distribution in the population has also effect, since the demands of children and of elderly persons are quite different. At present we have 35% of our population under 20, and 10% over 60. But in 1960 we shall have 29% of our population under 20, with 15% over 60. Other things equal, these differences in age distribution alone will have significant effect upon the intake of food, the food supply.

The state of the national income—the price level of foods and non-food goods and services and the index number of cost of living—influence the diet directly and indirectly, though the form and duration of occurrences may vary from case to case. If in deflation or inflation all prices were equally affected, no change in habits of consumption would be expected; but this is rarely the case, partly because lags occur and partly because different classes of goods and services, and especially different elasticities in use, react differently to price changes. The most striking illustrations of such changes occur in countries which have heavy exports or imports of foodstuffs. A population, or a group within a country, attempts to conserve its habits and customs under varying conditions of prices and purchasing power. But when finally this becomes impossible—and something approaching Engel's law comes into operation—then significant changes in the diet occur, and these may not be promptly reversed when conditions of prices and income return to more accustomed relations.

A particular factor in the changing diet lies in unemployment. It has been remarked that more changes occur during booms and depressions than under comparatively tranquil conditions. When ten million workers lose employment and go on relief, this necessarily brings a significant change in diet for many persons, unless the rationing of the unemployed is conducted according to the dictates of the science of nutrition. Paradoxically, war may bring about improvement in the diet, partly by absorption of the unemployed but also by extension of rationing to the civilian population. In the food

supply of the United States during the '40s, we are sure to find vestiges of changes introduced in the boom period of the '20s and in the depression of the '30s.

Varying prices in different food groups may introduce significant and continuing changes. Imagine the price of milk cut in half, the price of coffee doubled, the price of eggs trebled, or what not. In the majority of families, the attempt is made (in conscious or unconscious budget) to spend a constant proportion of income or constant amount of money, per week on the family food. A sudden cheapening stimulates demand, but it need not be proportional to price change. In particular, unequal elasticities in demand for various foodstuffs bring about different reactions within separate food classes in response to varying price changes. Prices of coffee, tea, cocoa, chocolate, oil seeds, and marine fats depend on rates of exchange; the foreign price of wool impinges on the domestic prices of lamb, and the export price of our cotton reacts on the price of cottonseed oil, and so forth. When changes in family income, cost of living, and price level are short-lived, customs and habits of eating need not be significantly altered; but when such changes are progressive and prolonged, they are likely profoundly to affect habits and customs. Possibly the best illustration of changes in the food supply thus induced are to be found in the field of beverages and delicacies.

- X. Over the past century, the most significant factors in changing the food supply of different countries has been the direct and the indirect effects of war. War rationing may change a diet for years after peace is re-established. This is due to the introduction of new foods, new processes, abolition of customs, and the cumulative influence of taste. The isolation of countries, the abolition of foreign trade and evolution of domestic substitutes, the depreciation of currencies and rationing of foreign exchange, the extraordinary increases in cost of transportation, the arbitrary controls of agriculture, and the priorities enjoyed by the military forces all combine to produce disruptions in production, distribution, price relations, and consumption of foodstuffs, which last for years or even decades. The food picture of the World War was profoundly changed by the World War, and will be changed by the World War, and will be changed again by the present war. The food supply of a world engaged in free trade between all countries would be vastly different from the food supply of the same world in which all countries strive for self-sufficiency in foodstuffs. The trade-war after war may be worse than trade-war during war. Surveying experiences in crop production in Europe over the past forty years, it is clear that the doctrine of "comparative advantage" is in eclipse, and pressure for production depends less on price than on other incentives. The net effect of this is to favor so-called "economic nationalism" in the food supply, both in peace and in war. Thus technology in peace prepares for war, and, after peace is resumed, is further developed because it has proved its worth in time of emergency. However, war can only retard but not nullify the broad trends—that production is expanding, distribution improving, processing being perfected, and technical information on nutrition being advanced in a population with lowered rate of growth, a lengthening span of life, and a rising standard of living.

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