



Journal of the Association of Food and Drug Officials

Serving the regulatory community since January 1937

Contents of this Issue

Page

From the Executive Director	1
2012-2013 AFDO Board of Directors	3
2012-2013 AFDO Board-Appointed Advisors.....	3
2012-2013 AFDO Committee Chairpersons	4
AFDO Regional Affiliates	5
2012 AFDO Award Recipients	6
2012 AFDO Resolutions	7
About the Authors	12
Glenn W. Kilpatrick Address.....	16
FDA Keynote	25
USDA Keynote	30
DHS Keynote	37
Health Canada Keynote	45
CFIA Keynote.....	51
Medical Devices in Canada	57
Temporary Foods in a Temporary Town.....	69
From the AFDO Archives (1939)	72
Common Food Infections.....	72
Select Abstracts of Papers Presented at the Forty-Second Annual Conference of the Association of Food and Drug Officials at Chicago, October, 1938, and at Local Conferences.....	76
AFDO Publications.....	80
Regulatory Guidance for Best Practices: Cottage Foods, Rev. April 2012.....	80
Requirements and Recommendations for Apple Cider Processing Operations, Rev. July 2012	92

From the Executive Director

Integration on the Horizon

AFDO is poised to work with a number of other entities to lead the country into the development of a national integrated food safety system. Remember, it was AFDO's vision some 14 years ago that first brought this concept up, and it will be AFDO that helps to usher this reform into being. You can look at many places where work is now underway and, everywhere you look, you will find AFDO's fingerprints.

So what's different today that was not there to support integration years ago? It's the Food Safety Modernization Act (FSMA) which mandates FDA to work within partnerships to achieve the requirements set by the statute. The primary partnership for FDA will be working with state and local governments who must now step up their programs to meet program standards, lab accreditation standards, and establish equivalency in their inspection and investigation efforts.

This will not be easy and will not occur in any quick fashion. It will develop through the work of many Workgroups, Alliances, and organizational efforts where you can find AFDO actively participating in. Here is a list of some of these groups:

1. International Food Protection Training Institute (IFPTI)
2. Seafood HACCP Alliance (SHA)
3. Produce Safety Alliance (PSA)
4. Food Safety Preventive Control Alliance (FSPCA)
5. Sprout Alliance
6. Manufactured Food Regulatory Program Alliance (MFRPA)
7. Partnership for Food Protection (PFP)
8. Integrated Food Safety Task Force
9. Building an Integrated Laboratory System to Advance the Safety of Food and Animal Feed

In addition to these, we have also become active in public health focused groups including the Council to Improve Foodborne Outbreak Response (CIFOR) and NoroCORE. AFDO is now considering establishing a new Committee that will focus on these and other public health activities.

Two major upcoming undertakings will be the "Integrated Food Safety System Toolkit" and the "Capacity Survey of State, Local, Tribal & Territorial Food and Feed Safety Agencies". These two critical pieces are foundational in first identifying needs and then beginning the process of integration within states, FDA Districts, and between the various food protection stakeholders.

The Toolkit will be rolled out at AFDO's Pre-Conference Workshop in Louisville, KY, next year. It is an effort started by IFPTI and will allow food protection stakeholders to conduct a self-assessment of their integration efforts, identify priorities, and identify steps to establish integration among stakeholders. It is a perfect fit with the many integration efforts currently in place, and it will provide direction to agencies, jurisdictions, and other stakeholders to begin to integrate. This may just be the "push" everyone needs to actually advance integration.

The survey AFDO will do for FDA is a requirement of FSMA and is another key information element needed for integration. Section 205(c)2 of FSMA requires that the Food and Drug Administration conduct a review of State and local capacities in order for them to develop and enhance these food safety and defense capacities. Information received from this survey will assist in the development and implementation of strategies that will help achieve the goals under an integrated food safety system. These include strategies to improve foodborne illness outbreak response, accelerate foodborne illness surveillance, strengthen inspection capacity of State and local agencies, improve the effectiveness of partnerships across governments to coordinate food safety and defense resources, and share information on a timely basis. Survey information will include both the current capacities as well as the current needs of State and Local regulatory agencies in terms of: staffing and expertise to perform food safety functions; staffing and expertise to perform food defense functions; laboratory capacity to support surveillance, outbreak response, inspection and enforcement; and information systems to support data management and exchange among regulatory agencies. This survey is targeted to begin this Fall.

We have our hands full, but we remain excited about the overdue food safety reform that is happening around us. We are clearly on the verge of fulfilling the vision we offered those many years ago.

We recognized we could use some help, so the staff of AFDO wishes to congratulate Doug Saunders on his retirement from the Virginia Department of Agriculture & Consumer Services ,and to welcome him as the newest member of the AFDO staff. Doug will assume the responsibilities of Project Manager for the Manufactured Food Regulatory Program Alliance (MFRPA) where he will lead that group in advancing elements of a nationally integrated food safety system. That work should be very easy for Doug, as he was one of the early pioneers for AFDO in advancing our vision some 14 years ago. Doug was one of the first state representatives to serve on the National Food Safety System (NFSS) Steering Committee where he guided the many integration projects and efforts that were occurring. Much of what began back then is being advanced once again today through groups such as the Alliance. AFDO and its membership are so lucky to have him become a member of our hard working staff.

There is so much more I could tell you about AFDO – but you can see us or hear about us for yourself if you are involved in any of the many efforts designed to create an integrated food safety system or advance food safety reform. It's what we always wanted, it's what we always fought for, and now it is right there on the horizon. You should truly be proud of AFDO.

Joseph Corby
AFDO Executive Director

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Dennis Baker, U.S. Food & Drug Administration

Cynthia Culmo, Abbott Laboratories

Sarah Geisert, General Mills, Inc.

Kent Kitade, California Department of Food & Agriculture

Jerry Wojtala, International Food Protection Training Institute

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2012 AFDO Award Recipients

The **Elliot O. Grosvenor Food Safety Award** was presented to the **Indiana State Department of Health**. Mr. Scott Gilliam, Program Director, accepted the award on behalf of his 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, **Gerald Wojtala**, was honored for his outstanding service and devotion to the administration of food, drug and consumer protection laws of our country. Mr. Wojtala served the Michigan Department of Agriculture prior to joining the International Food Protection Training Institute in Battle Creek, MI.

The **Associate Member Award** was presented to **Stan Hazan**, Senior Director of Regulatory Affairs for NSF International in Ann Arbor, Michigan. 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 2012 **Achievement Award** was presented to **Joetta Lynn DeFrancesco**, Senior Sanitation & Safety Specialist with the Florida Department of Agriculture and Consumer Services, Bonita Springs, FL. The Achievement Award is annually bestowed on an individual who has demonstrated exemplary performance within their field in their first five years of service.

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

Kristina Underthun, University of Florida, Gainesville, FL

Ariana Ramdin, University of Florida, Gainesville, FL

Corrie Donnell, St. Louis University, St. Louis, MO

2012 AFDO Resolutions

RESOLUTION NUMBER 2012-01

Submitted by: AFDO Food Committee

Date: March 15, 2012

Concerning: Food Freedom Laws

Whereas, the Association of Food & Drug Officials (AFDO) is a major supporter and promoter of a national integrated food safety system, and

Whereas, AFDO recognizes the critical importance of applying uniform rules by all levels of government as part of the foundation to a national integrated food safety system, and

Whereas, AFDO firmly believes it is not unreasonable to require any entity that sells food for human consumption to be responsible for the safety of that food, and

Whereas, a number of state legislative proposals known as “Food Freedom Laws” are aimed at eliminating government involvement in regulating small businesses or farmers that are involved in the marketing of food for human consumption, and

Whereas, several of these proposed rules go as far as possible imprisonment for violators of these proposed rules such as state and federal government regulatory officials, and

Whereas, the fragmentation of state and national food safety laws that would be caused by allowing these numerous individualized laws to exist across the country would be damaging to the advancement of a national integrated food safety system, and

Whereas, there already exist current means and provisions to produce, manufacture and sell locally grown/produced foods freely that are in harmony with federal and state laws, therefore

Be it resolved, that AFDO write to the National Council of State Legislatures (NCSL) and state food safety agencies and advise them of AFDO’s concern with Food Freedom Laws and the potential harm they would create for advancing a national integrated food safety system, and

Be it further resolved, that AFDO advise FDA and USDA of our position on Food Freedom Laws and ask that they support AFDO on this position.

RESOLUTION NUMBER 2012-02

Submitted by: AFDO Board of Directors

Date: April 15, 2012

Concerning: State Rapid Response Teams

Whereas, there exists an increased national focus on emergency preparedness and response relative to our food safety system and supply ever since the attack on Sept 11, 2001, and

Whereas, 9 pilot states agreed to participate in a Rapid Response Team (RRT) program and strengthen their food defense program infrastructure and work towards an integrated food safety system as required by the Food Safety Modernization Act (FSMA), and

Whereas, these pilot states agreed to conduct and submit yearly self-assessment plans, participate in audits to measure deliverables and develop, implement, and sustain replicable model RRT concepts for adoption or use by other states, and

Whereas, a study conducted within the Fellowship for Food Protection to evaluate challenges that exist with the pilot states to properly complete deliverables in the RRT program revealed the following concerns:

- States cannot continue to develop, implement and maintain an effective integrated food safety system without sustainable funding
- States have been primarily focused on the required grant deliverables that do not reflect some of the new recommendations that have resulted from learned lessons
- Written plans and strategies increased faster responses
- States can strengthen their RRT and meet training event requirements by conducting an After Action Report and team review of real food emergencies, and

Whereas, AFDO acknowledges that FDA is expanding the number of Cooperative Agreements for additional RRT's, therefore

Be it resolved that AFDO advise FDA of the critical importance of sustainable federal funding as necessary for long term planning, continued development and continued maintenance of a safe food supply, and

Be it further resolved that AFDO advise FDA that component recommendations that have arisen out of learned best-practices should be incorporated into new RRT grant deliverables, and

Be it further resolved that AFDO, through the Manufactured Food Regulatory Program Alliance, continue to provide a conduit to share RRT recommendations with all state programs.

RESOLUTION NUMBER 2012-03

Submitted by: AFDO Board of Directors

Date: April 15, 2012

Concerning: Testing for non-O157:H7 Shiga toxin-producing *Escherichia coli* serotypes

Whereas, *E. coli* O157:H7 is a common strain associated with foodborne illness and deaths in the United States, and

Whereas, Australia, Argentina, and Canada report non-O157:H7 Shiga-toxin *E. coli* (STEC) infections to be as prevalent or more prevalent than O157:H7, and

Whereas, pathogenic non-O157:H7 strains of *E. coli* are not routinely tested due to the difficulty in identifying and confirming them from the non-pathogenic STEC and the lack of reliable, validated laboratory methods and

Whereas, ground beef, unpasteurized milk, fermented meat products, and apple cider have historically been associated with STEC infections with ground beef having been associated with more STEC outbreaks than any other food product and

Whereas, sampling and testing of ground beef has revealed a number of concerns including test kit weaknesses, shortcomings with screen and confirmation methods, and the need for additional validation and real-life analyses to identify and address weaknesses, therefore

Be it resolved that AFDO advise USDA/FSIS that more effort to research and validate testing is needed and that FSIS should work with and share test materials with state labs in order to address this matter, and

Be it further resolved that AFDO recommend to USDA/FSIS that they consider working in conjunction with state programs to conduct validation studies in state-accredited (ISO 17025) labs to attempt to identify and address weaknesses in both the screening and confirmation steps.

RESOLUTION NUMBER 2012-04

Submitted by: AFDO Board of Directors

Date: April 15, 2012

Concerning: Aflatoxin

Whereas, aflatoxin is a naturally occurring toxic metabolite produced by mold infestations that typically affects corn and peanuts which are ingredients used in both food and feed products, and

Whereas, aflatoxin is a known carcinogen and has been associated with various diseases, such as aflatoxicosis, and

Whereas, consumption of products contaminated with aflatoxin pose a health concern to both humans and animals, and

Whereas, products that are deemed adulterated by the food industry or by regulation may be allowable as a product in the feed industry, and

Whereas, identifying and utilizing the aflatoxin knowledge of industry, agencies can focus on the most effective way to address the educational gaps between occurrence and prevention of aflatoxin in the food and feed supply chain, therefore

Be it resolved that AFDO recommend that FDA provide technical information on aflatoxin occurrence and prevention as well as on conducting hazard analyses and sampling protocols to the states for distribution to the feed and food industries and to the Food Safety Preventive Controls Alliance for inclusion in industry Hazard Analysis training and technical assistance.

RESOLUTION NUMBER 2012-05

Submitted by: AFDO Board of Directors

Date: June 5, 2012

Concerning: Training Industry to Participate in an Integrated Food Safety System

Whereas, the Food Safety Modernization Act (FSMA) has established a statutory framework for development of an Integrated Food Safety System comprised of federal, state, territorial, tribal and local agencies with food safety responsibilities, and

Whereas, a key requirement of FSMA is a focus on preventing food safety problems rather than relying primarily on reacting to problems after they occur, and

Whereas, industry has the primary responsibility for growing, processing, transporting, and marketing safe food on a local, regional, national and global basis, and

Whereas, an integrated food safety system will require strong working partnerships among all stakeholders, including industry, to be successful, and

Whereas, AFDO believes that joint training, when appropriate, with governmental food safety officials is necessary for ensuring that regulators and industry have a common knowledge and skills baseline for preventing and addressing food safety incidents and protecting public health, and

Whereas AFDO supports the inclusion of industry considerations and participation, where appropriate, in the curriculum planning, course development, and delivery of training initiatives undertaken within FDA's Integrated Food Protection Training and Certification System, and therefore

Be it resolved that joint training of regulators and industry should be encouraged in Food Safety Modernization Act initiatives such as the Preventive Controls Alliance, the Produce Safety Alliance, the Manufactured Food Regulatory Program Alliance, the Sprout Alliance, and the Seafood HACCP Alliance, and

Be it further resolved that training built for regulatory or industry purposes meets quality and content standards being developed by the International Food Protection Training Institute under FDA's Integrated Food Protection Training and Certification System, and

Be it further resolved that AFDO advise the Food and Drug Administration and the U.S. Department of Agriculture of the need to support inclusion of industry, where appropriate, into training developed for and offered to regulatory officials.

About the Authors

Deborah M. Autor, Esq., is FDA's Deputy Commissioner for Global Regulatory Operations and Policy and has been with the FDA for over 10 years. Ms. Autor's Directorate, one of four created in July 2011, includes the Office of Regulatory Affairs and the Office of International Programs. She leads FDA's strategy for confronting the challenges of globalization and import safety and she co-chaired the group that prepared FDA's June 2011 report, Pathway to Global Product Safety and Quality, which describes the paradigm shift that FDA must make to face the challenges of globalization today and in the future.

Prior to being named Deputy Commissioner, Ms. Autor served for five years as the Director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research.

Before joining the FDA, Ms. Autor was a trial attorney for seven years at the U.S. Department of Justice, where she litigated civil and criminal cases on behalf of FDA and other federal law enforcement agencies.

Ms. Autor was awarded the 2011 Meritorious Executive Presidential Rank Award; the 2011 Food and Drug Law Institute's Distinguished Service and Leadership Award; and was a 2010 finalist for the prestigious Service to America Medal.

Ms. Autor obtained her B.A. from Barnard College of Columbia University and her J.D. *magna cum laude* from Boston University School of Law where she was an Article Editor for the Boston University Law Review.

Dr. Alexander Garza is the assistant secretary for health affairs and chief medical officer of the Department of Homeland Security. He manages the Department's medical and health security matters, oversees the health aspects of contingency planning for all chemical, biological, radiological and nuclear hazards, and leads a coordinated effort to ensure that the Department is prepared to respond to biological and chemical weapons of mass destruction.

Prior to joining the Department in August 2009, Dr. Garza spent 13 years as a practicing physician and medical educator. He most recently served as the director of military programs at the ER One Institute at the Washington Hospital Center, and has served as the associate medical director of the emergency medical services (EMS) for the state of New Mexico, and director of EMS for the Kansas City, Missouri, Health Department. While practicing medicine he also served as a professor at leading medical institutions including Georgetown University, the University of New Mexico and University of Missouri - Kansas City.

Dr. Garza served in the U.S. Army Reserve and was a battalion surgeon and public health team chief during Operation Flintlock in Dakar, Senegal. He also served as a public health team chief during Operation Iraqi Freedom and as a special investigator and medical expert for Major General Raymond Odierno. He coordinated the development of a website that facilitated the donation of more than one million medical books to

Iraq. Dr. Garza earned over a dozen awards including the Bronze Star and Combat Action Badge.

Dr. Garza holds a medical degree from the University of Missouri - Columbia School of Medicine, a Master of Public Health from the Saint Louis University School of Public Health and a Bachelor of Science in biology from the University of Missouri - Kansas City. Prior to earning his M.D., he served as a paramedic and an emergency medical technician. He is a fellow in the American College of Emergency Physicians, and a member of the American Public Health Association and other health organizations. He is a Senior Editor for the Oxford Handbook in Disaster Medicine and has authored numerous chapters in medical texts and published multiple articles and peer-reviewed publications. He has lectured nationally and internationally about emergency care and disaster medicine. He is a recipient of the American Heart Association's Young Investigator Award, a White House Commendation for Drug Demand Reduction and numerous awards for his work in emergency medicine.

Paul Glover was appointed Assistant Deputy Minister (ADM) of the Health Products and Food Branch (HPFB) at Health Canada in February 2011. HPFB takes an integrated approach to managing the health-related risks and benefits of health products and food through the regulatory system. The Branch also promotes conditions that enable Canadians to make health choices and provides information so that they can make informed decisions about their health.

Paul was the ADM of the Healthy Environments and Consumer Safety Branch at Health Canada from September 2008 to January 2011. Prior to that, he was in the Privy Council Office's Operations Branch, where he worked on a wide range of social policy issues. He began his career at Health Canada in 1986, in the informatics area. Paul then moved on to health systems management and assumed progressively more responsible jobs, eventually leading a number of business units as Director General, including First Nations and Inuit Health Programs, the Non-Insured Health Benefits Program, and the Safe Environments Program.

Over the years Paul has served on numerous governing bodies, including the Board of Directors of the Queensway Carleton Hospital, the Advisory Board for the Canadian Institutes of Health Research, and the Queen's University Board of Directors for the Centre for Water and the Environment. He has been a member of the National Academies of Science in the U.S.A. and the International Joint Commission.

Paul earned his Master in Business Administration from Queen's University.

Dr. Elisabeth A. Hagen was sworn-in as Under Secretary for Food Safety on Friday, August 20, 2010. In this position, she oversees the policies and programs of the Food Safety and Inspection Service (FSIS), USDA's public health regulatory agency that ensures the nation's commercial meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged. She also chairs the U.S. Codex Steering Committee, which provides guidance to U.S. delegations to the Codex Alimentarius Commission.

Since joining federal government in 2006, Dr. Hagen has advanced a science-based, public health agenda at USDA. She directed mission-critical outbreak and consumer complaint investigations, oversaw agency risk assessments and regulatory testing programs, and led key policy development efforts for emerging public health issues as a senior executive in the FSIS Office of Public Health Science, most recently as Deputy Assistant Administrator. Prior to her appointment as Under Secretary, she served as USDA's Chief Medical Officer, advising FSIS and other USDA mission areas on a range of human health issues, such as food safety, nutrition, and zoonotic diseases.

Dr. Hagen has also been actively involved in interagency efforts to better protect the public from foodborne illnesses, including the Foodborne Diseases Active Surveillance Network (FoodNet) Steering Committee, which guides the work of the nation's premier foodborne illness monitoring system. She was also a member of the Council to Improve Foodborne Outbreak Response (CIFOR), a national collaborative effort to detect, investigate, control, and prevent foodborne disease outbreaks.

Before joining public service, Dr. Hagen taught and practiced medicine in both the private and academic sectors. In addition to several hospital and university appointments, her experience includes research and publications in infectious diseases and providing medical care to underserved populations.

Dr. Hagen holds an M.D. from Harvard Medical School and a B.S. from Saint Joseph's University. She completed specialty medical training at the University of Texas Southwestern and the University of Pennsylvania, and is board certified in infectious diseases.

Cameron Prince took on the important task of moving the CFIA's Modernized Inspection System initiative ahead as Vice President, Inspection Modernization. After 18 years working in various positions with Canada's Department of Fisheries & Oceans, Cameron joined the CFIA at its formation in 1997 and has held such positions as Vice President, Operations Branch; Executive Director, Operations Coordination; Executive Director, Atlantic Operations; and Executive Director, Animal Products Directorate.

Cameron's first Government of Canada position was with the Department of Fisheries & Oceans in 1978 as a Fish Inspector in Windsor, Ontario. Cameron has a Bachelor of Science Degree in Zoology (Honours) from the University of Western Ontario. Cameron's interests include building, restoring and sailing wooden boats, fly fishing and making maple syrup.

Chris Rose received a Bachelor of Science in Biology from Saint Mary's University and a Master of Applied Science in Biomedical Engineering from Dalhousie University. He is also a certified Six Sigma Black Belt and Tissue Bank Specialist.

Chris joined Health Canada in 2006 as a Medical Device Specialist and is currently the manager for the Medical Device Compliance Unit. Prior to joining Health Canada, Chris has had working experience in the clinical environment with the Capital Health District Authority in Halifax, Nova Scotia and with private industry as a Quality Engineering Team Leader for Johnson & Johnson in Raynham, Massachusetts.

Howard Sklamberg, J.D., has been Deputy Associate Commissioner for Regulatory Affairs at the Food and Drug Administration since July 2011. He is the principal deputy to the Associate Commissioner who leads the Office of Regulatory Affairs, which has a staff of over 4,300 employees across the United States and jurisdiction over operations, policy, and science related to domestic and foreign inspections, imports, regulatory and criminal enforcement and recalls. From May 2010 to July 2011, Mr. Sklamberg was Director of FDA's Office of Enforcement.

Mr. Sklamberg was a federal prosecutor from 1998 to 2010, serving as an Assistant United States Attorney for the District of Columbia and as a Trial Attorney in the Justice Department's Public Integrity Section. He was the sole or lead counsel in over 40 criminal trials. Between 2007 and 2010, Mr. Sklamberg was Deputy Chief of the Fraud and Public Corruption Section of the United States Attorney's Office. Since 1999, Mr. Sklamberg has been an Adjunct Professor at American University's Washington College of Law, where he has taught Congressional Investigations and White Collar Crime. From 1997 to 1998, Mr. Sklamberg was Minority Counsel on the U.S. Senate Committee on Governmental Affairs.

Mr. Sklamberg has a B.A. from Yale University, a J.D. from Harvard Law School, and an M.A. from the Fletcher School of Law and Diplomacy.

Glenn W. Kilpatrick Address
Deborah M. Autor
Deputy Commissioner for Global Regulatory Operations and Policy
U.S. Food and Drug Administration
AFDO 116th Annual Educational Conference
Providence, RI -- June 3, 2012

(transcribed)

Thank you, Oscar, for that kind introduction.

It's an honor to be here with you today. AFDO has played such an important role over the years by fostering national uniformity in food and medical product regulation and by fostering integration of federal, state, and local food safety activities.

AFDO is a truly unique organization, and you are to be congratulated – and thanked – for your many notable public health initiatives involving food and drug officials from all across the nation and all levels of government.

Glenn W. Kilpatrick

As was mentioned, I am here to present the Glenn W. Kilpatrick Memorial Address. In preparing to be here today, I've learned about Mr. Kilpatrick's approach and his vision. That approach and vision are as applicable today as they were decades ago.

Mr. Kilpatrick worked at FDA during the 1960s and 1970s, and he established many of the cornerstones of the relationship between FDA and the States. First, he recognized the importance of communication between FDA and the States. He planned and inaugurated a system of rapid communication between FDA headquarters, regional and district offices, and key State offices. He also instituted planning and informational conferences between associations of State and local officials and the FDA, as frequently as he could. These kinds of efforts continue today, as you well know.

But Mr. Kilpatrick went much further than instituting better communications; he had the vision that the Federal government and the States could share responsibility in areas where our authorities overlap. He significantly increased the commissioning of State officials so that they could carry out activities on behalf of FDA. Building on that, Mr. Kilpatrick originated the program, still in existence today, through which FDA contracts with the States to carry out inspection activities. This approach has significantly expanded the inspectional coverage of FDA-regulated goods and firms over the years.

Mr. Kilpatrick worked towards a future in which the Federal and State governments could collaborate more closely, each bringing its own strengths to a mutually beneficial partnership for public health protection.

The Impact of Globalization

Today, FDA faces a new challenge: the challenge of globalization, which did not really exist during Mr. Kilpatrick's time. Globalization affects every type of product FDA regulates, and it demands a major change in the way FDA does business. The example of Mr. Kilpatrick's work is very relevant, as I will explain.

The world was a very different place when President Franklin Delano Roosevelt established the modern FDA in 1938, and likewise in the 1960s and 1970s when Mr. Kilpatrick served in FDA. In those days, FDA products were overwhelmingly manufactured within the United States, and the volume of FDA-regulated imports was low.

Today, however, that picture has changed drastically. FDA is grappling with the challenges of global supply chains, international trade, and foreign sourcing of FDA-regulated products. Just as public health leaders have long recognized that disease knows no borders, we now see that product development and product safety and quality no longer begin or end at the border.

The United States now imports 40 percent of finished drugs, and a stunning 80 percent of the manufacturers of active pharmaceutical ingredients in our drugs are located outside our borders. Similarly, for medical devices, half of all devices used in the United States are now imported.

Turning to the foods area, 10 to 15 percent of the food consumed by U.S. households is imported, and when we look at some individual food products, the level of imports is much higher. Approximately 50 percent of fresh fruits and 20 percent of fresh vegetables come from abroad. And 80 percent of seafood eaten in the United States is imported.

FDA-regulated products now originate from more than 150 countries, 130,000 importers, and 300,000 foreign facilities. Not only are more finished products imported, but manufacturers increasingly use imported materials in their U.S.-based plants. In addition, in the foods area, U.S. firms are making business decisions to take raw materials grown or raised in the United States and ship them overseas for processing. Those products are then being shipped back to the United States 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, and we are seeing increasing numbers of firms involved in the production of a single product. In the foods area, the production of a single commodity such as a can of tuna can involve the efforts of multiple parties from different geographic regions who fish, process, can, or distribute the product. The fish might be caught in the South Pacific and processed into frozen pieces. It may then 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 the East Coast of the United States and from there distributed throughout the rest of the country, where consumers buy it for their meals. Our foods and medical products are truly world travelers.

In these types of international supply chains, regulators face the question of how to deal with the risks of the unknown with respect to product quality and integrity – Who has handled the product? How was the product manufactured, packed, distributed, and stored? Who supplied the ingredients?

Increased complexity can also present challenges to product safety and security. Increasingly, regulators – as well as industry – must contend with ever more sophisticated threats of fraud, product adulteration, and even terrorism. And the reality is that manufacturers and others in the supply chain around the world may place economic gain above safety and public health or have more malevolent motivations.

Moving FDA Towards a Global Operations Paradigm

FDA has established a number of significant building blocks during the past decade to address the challenges of globalization. First, we have engaged very actively in global harmonization initiatives, through which FDA and its partners have developed common standards. Second, FDA has signed 54 arrangements that enable the exchange of confidential information with foreign regulators in 23 countries, the European Union, and with a few multilateral organizations such as the World Health Organization. These arrangements, similar to our agreements with the states or the commissioning of state officials that Mr. Kilpatrick initiated, permit FDA and regulators to work together more closely and effectively. Third, building on the confidentiality arrangements, FDA has developed many highly effective bilateral relationships and some multi-lateral relationships with its foreign counterparts.

Finally, in the last few years, FDA has established a foreign presence, with 13 FDA posts in other countries. FDA staff who are stationed abroad work to increase our cooperation with foreign regulators, build FDA's knowledge of foreign industry practices, educate foreign industry about U.S. requirements, provide technical assistance to foreign governments, and conduct a portion of the agency's foreign inspections.

Examples of all of these key building blocks are highlighted in a report recently published by FDA entitled "Global Engagement." You will find copies of the report in the hallway after my talk.

All of FDA's international activities that I've mentioned are very significant. Yet, I call them "building blocks" for a reason: They have established valuable mechanisms for working with the international community, and now we need to further expand the use of such mechanisms and use the lessons we have learned from our domestic and international partnerships to build an even more integrated system of working with our international regulatory partners. In light of the huge scope of the globalization challenge we face, it is clear that we must find a way to leap-frog ahead.

FDA's Commissioner, Dr. Margaret Hamburg, has made FDA's response to globalization one of her top priorities. In late 2010, Commissioner Hamburg established the Globalization Steering Committee, a cross-section of Agency experts tasked with developing a framework and action plan to guide FDA's future regulatory strategies for imported products.

The Committee released a report, entitled “Pathway to Global Product Safety and Quality,” which sets forth a plan for the FDA to proactively anticipate and prevent the arrival of harmful products into the U.S. marketplace. The report describes how FDA will transform itself from a domestically-focused agency to a public health regulatory agency fully prepared for a complex, globalized regulatory environment. The ultimate goal is to move from a primarily domestic orientation to one that treats like risks in equivalent ways, regardless of geographic location. Copies of that report are also available in the hall.

The Commissioner has also created an organizational structure to facilitate implementation of the “Pathway Report.” As part of an agency reorganization, she established my new position, Deputy Commissioner for Global Regulatory Operations and Policy. My directorate, which is one of four that now comprise the agency, includes both FDA’s Office of International Programs, which leads the agency’s global engagement work, and the Office of Regulatory Affairs, which is our field component and provides leadership on imports, inspections, and enforcement policies.

Commissioner Hamburg has charged my directorate with making FDA’s response to globalization and import safety a top priority. The Commissioner directed us to implement the recommendations in the Pathway Report and to ensure that FDA fully integrates its domestic and international programs to most effectively promote and protect public health.

Thus, the groundwork has been laid for FDA to implement a new strategy for global product safety and quality.

Pathway Report

Since the Pathway Report is so central to the work of the new directorate, let me take a few moments to describe its core tenets to you. The report presents a strategy with four distinctive components, or “pillars.”

The first pillar involves the creation of global coalitions of regulators focused on ensuring and improving global product safety. As I mentioned, over the past decade, FDA has typically engaged in close cooperation with a number of regulatory partners via bilateral agreements. We now envision a much deeper engagement, beginning with a core group of partners. A primary aim of these coalitions would be to develop procedures for more comprehensive and systematic information sharing and coordinated deployment of resources. The goal for FDA is mutual reliance. We cannot do it all alone. We need to learn from others, work with others, and leverage resources globally.

By the way, this is not so dissimilar from what Mr. Kilpatrick, whom we are honoring today with this presentation, was trying to do. In his world, where most FDA-regulated products were produced domestically, in the States, Mr. Kilpatrick had a vision of increased partnership between FDA and the State governments. Today, when so many FDA-regulated products on the U.S. market are produced in foreign countries, we are envisioning increased partnership with foreign governments, as well as with the States.

Getting back to the pillars of the Pathway Report, the second pillar of our global strategy involves building global data systems and networks and proactively obtaining data from our foreign regulatory partners and sharing data with them. It is essential that the Agency be able to aggregate and analyze multiple sources of information to identify risks and emerging trends. We need to identify critical data elements, better standardize our reporting, and create properties for regular systemic information exchanges. This would include the use of unique facility identifiers, perhaps Dun and Bradstreet's D-U-N-S numbers that could enable us to crosswalk data coming from multiple sources about a single facility.

Ultimately FDA will work with its regulatory partners to develop a process for regular, systematic information exchange that will provide essential inputs into FDA's risk modeling and analyses.

The third pillar of the Pathway Report involves the expansion of intelligence gathering, with an increased focus on risk analytics and thoroughly modernized IT capabilities. Risk analytics can inform our priorities in inspections, training, regulatory cooperation, and surveillance efforts. As we monitor and analyze data, we must also work proactively to identify vulnerabilities and increase our capabilities to interpret and act on such data. FDA has been doing risk analytics for a long time, but we want to take a more proactive, systematic, and global approach.

The fourth and final pillar of the Pathway Report involves leveraging the efforts of public and private third parties. One of the most fundamental changes that FDA will undertake is a more effective deployment of its own resources. We need to ensure that our standards are well understood and fully applied, foster best practices in industry, and foster innovation to drive safety and quality. In addition, FDA intends to establish relationships with third parties on whom we can rely, create a review and audit infrastructure to verify the integrity of the information that we receive from public and private third parties, and ensure that the Agency can act on that information.

We at FDA believe that the four pillars I've briefly described will move FDA towards strategic and risk-based global industry oversight. The Agency will continue executing the broad range of surveillance, intervention and enforcement activities that are currently in its toolbox for preventing product-related harms. However, we need to think more creatively about what other tools we can deploy to maximize product quality and safety. We will have considerably more information at our fingertips to conduct risk analysis and determine the relative magnitude of risks. We will create tailored, flexible strategies for addressing risks, and we will do so with our many partners.

Federal-State Partnership

With that, I'd like to take a few minutes to talk about Federal-State cooperation. And when I use the terms "States" and "State governments," these are short-hand terms that I'm using to include regulatory and public health officials in the States, localities, territories, and tribes.

Even in a global economic system with an increasing amount of product coming into the United States from abroad, FDA cooperation with the States continues to be absolutely vital. State governments are performing surveillance, conducting inspections, testing products, and giving FDA feedback that is truly essential for assuring the safety of products on the U.S. market. Federal-State cooperation enhances consumer protection by expanding the product safety net.

Cooperation in the foods area is particularly crucial at 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 by the Food Safety Modernization Act as part of a new regulatory paradigm for foods.

In this regard, FDA remains committed to the Partnership for Food Protection, which has done a terrific job in moving us forward collectively towards an integrated food safety system – and by “us,” I mean four Federal agencies, and state, local tribal, and territorial entities. FDA has convened two 50-State meetings in conjunction with the Partnership for Food Protection; these meetings brought the groups together to develop recommendations for advancing the integrated food safety system. Ten working groups, with joint Federal/State/local leadership, then do the hard work of developing national standards, guidances, standardized procedures, training programs, collaborative work assignments, and other tools to implement the 50-State recommendations. It’s been a tremendous and very fruitful undertaking, and FDA remains committed to the Partnership’s efforts.

FDA also remains committed to other initiatives that advance Federal-State integration. One important example is the placement of dedicated State liaisons in FDA’s district offices. The State liaison positions were created to serve as centralized points of contact at the district level to ensure effective collaboration and coordination of FDA activities with State programs.

Another example of FDA’s commitment to advancing Federal-State integration is the creation of Rapid Response Teams. Through a multi-year cooperative agreement, FDA is supporting the development of nine of these teams, which conduct integrated, multi-agency responses to food and feed emergencies. Because of the success of these nine initial Rapid Response Teams, FDA is planning to support up to five more teams in 2012.

In addition, as many of you may be aware, FDA awarded a cooperative agreement to AFDO in 2011 under the “Alliance for Advancing a National Integrated Food Safety System Cooperative Agreement Program.” In addition to other activities, the award funds AFDO to work with FDA to establish a network of manufactured food program managers and to host an annual program managers training to build operational and strategic partnerships. In addition, AFDO and FDA will develop and implement pilot projects to support the adoption of the Manufactured Food Regulatory Program Standards by State and local governments and to collaborate with other partners to identify, develop and deliver food safety and defense training programs.

This cooperative agreement with AFDO is an important step. But at the same time, we in FDA recognize that we must go much, much further in terms of cooperation and integration with State and local governments. To that end, Commissioner Hamburg has established an Integrated Food Safety System Task Force, which has been studying how the States and FDA can work best together.

The Task Force will identify the enhancements needed to ensure full adoption of an integrated food safety system. The Task Force is analyzing the current state of the Federal-State partnership and will produce both short-term and long-term recommendations.

I personally am very interested in seeing some robust and useful recommendations from the Task Force. I fully agree with the State and local officials who have called for strengthening Federal-State integration, improving communication, and transforming our partnership into one that operates more seamlessly and effectively, supported by strong, positive working relationships between our people and our organizations.

We all have limited resources, and consumers are depending on the leveraging of all of those resources – Federal, State, and local – to build a strong and vibrant food safety system.

Bringing It All Together

Up to this point in my remarks, I've been talking about FDA-international partnerships and Federal-State cooperation largely as two separate creatures. In fact, that's how these subjects are usually discussed. Certain sets of people pay close attention to Federal-State integration, and other sets of people think about Federal-international partnerships.

In fact, there are many parallels between what FDA and the States have done and are doing together, and the effort FDA is embarking on in the international arena. Federal-State cooperation through the Partnership for Food Protection provides an interesting model for the broad global coalitions that FDA intends to develop. The collaboration between FDA and the States in information sharing, intelligence signals, and leveraging of resources, and the mutual reliance we have developed, provide lessons that can be applied internationally. FDA's State liaisons, who work with State regulatory partners, share similarities with FDA's foreign posts, which work with foreign regulatory counterparts. The challenges posed by IT systems and exchange of confidential information are similar, whether looked at from a national or international perspective. FDA's end goals - mutual reliance and equivalent treatment of like risks - are the same, whether in reference to the States or to foreign countries.

While development of FDA's international operating model is evolving, we - those of us in FDA and in the States - need to begin exploring where specific overlaps exist between FDA-State cooperation and FDA-international cooperation and how we will deal with them. Let me give you a couple of examples.

First: FDA and the States are working on models for collecting and sharing data in a systematic way. We need to think in terms of models that will also be able to incorporate international data sharing.

Here's another example: As you know, quite a bit of work has been done on Federal-State integration in the area of laboratory cooperation through the Food Emergency Response Network (FERN) and the Electronic Laboratory Exchange Network (e-LEXNET). These are innovative programs that permit a more integrated laboratory response to food emergencies, as well as a data-sharing system that permits governments to share analytical results for foods, so that outbreaks of food-borne illness can be more readily detected. While working on increased laboratory integration within the United States, we also need to consider laboratory integration internationally and how it might mesh with our program for domestic laboratory integration.

We in FDA and the States need to develop responses to these issues and to identify other key issues that will need to be addressed.

Globalization impacts us all. In fact, I would challenge us to try to stop thinking of federal-state and federal-international as two different, perhaps overlapping areas of cooperation. In the long run, Federal agencies, States, localities, territories, and tribes, and our counterparts all around the world should form one network protecting our respective consumers, as well as consumers worldwide. We have in this room the brainpower to figure out how to bring it all together, and I can assure you that FDA will be very interested to hear about further thinking in this area.

Conclusion

To conclude, I want to re-emphasize a few key points.

Because of the fundamental changes brought by globalization, FDA must change the way it fulfills its mission to promote and protect the health of the American people. Over the next decade, FDA will transform from a predominantly domestically-focused Agency operating in a globalized economy to a public health regulatory agency fully prepared for a complex globalized regulatory environment.

At the same time, Federal-State integration will receive even more emphasis than in the past, as Federal, State, and local officials work together to strengthen the national regulatory system for food safety. And, FDA needs to take the lessons learned from working with our states to build an integrated system and apply it globally.

Lastly, we must think about how our Federal-State partnership can account for international issues. In some cases, this will mean expanding Federal-State mechanisms to incorporate global considerations. In other cases, it will mean considering how FDA's growing partnerships with the international community may affect the States. At some point, I hope it will also mean having a discussion about more integration between the Federal-State partnership and FDA's international partnerships.

I wish that Glenn Kilpatrick could be here to see our efforts. I feel sure that he would approve of them because they continue to implement his vision. Mr. Kilpatrick envisioned that public health protection could be improved through partnerships between regulatory agencies with overlapping missions. He championed the sharing of information and leveraging of resources. I believe, too, that he envisioned that partnerships would have a multiplier effect, so that the whole would be greater than the sum of its parts. And that is also what FDA is hoping to achieve.

This is a challenge requiring all of us to work together. The return on investment will be safer and higher quality products and increased safety and security for U.S. consumers and patients, as well as citizens worldwide.

FDA Keynote
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U.S. Food and Drug Administration
AFDO 116th Annual Educational Conference
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(transcribed)

Good morning everyone and thank you, Steve, for the introduction. I first want to point out that Dara Corrigan, my boss, was initially going to do the keynote speech, but she had to attend to a family emergency.

You heard yesterday from Deb Autor about the Pathway Report and the challenges we all face from an increasingly globalized market in food and medical products and what that means as far as our collective ability to do our jobs to protect public health. I won't reiterate what Deb said, but there are a few points I want to build on today and that will probably be built on by others throughout the conference. Deb had talked about the importance of coalition building and on mutual reliance. That extends as you follow the life cycle of food or medical products from where it is grown or produced in some place far away through all kinds of transport points until it reaches the shelf and is in someone's medicine cabinet or kitchen. And all of the points along that route are opportunities for us to do our jobs – "us" being the collective us; people overseas, Federal government, State and local governments, and, indeed, private third parties. Given the fact that we have an increasingly complex task, the fact that we work together and mutually rely on each other isn't a luxury anymore, it is an absolute necessity, and we will categorically fail in our mission to protect public health if we don't build our mutual reliance increasingly just as our challenges keep growing and growing.

Deb had also talked about being risk-based and gathering intelligence to do our jobs. As we know, we can't, nor should we, be everywhere at a time of difficult budgets. I am not an economist, but I can see the future well enough to know that it is going to be true for quite some time. We are not going to have huge new resources going into our work and that means we have to target very effectively, again mutual reliance, on the most important points in those supply chains and to target risk so that we can use our resources most efficiently to protect public health.

I want to give a few examples from different areas about how we in fact do this. It's my observation, and I've been in FDA for two years, that what we are talking about is both incredibly important and actually incredibly obvious, and that it has been done over and over again in other areas and walks of life that we have seen and don't even think about. I'll start with a story. I remember when I was learning to drive, my father said to me that a car is not a toy; you have to be careful, obey the speed limit, and that sort of thing. He still does drive very slowly, so he practices what he preaches. I had a different relative that told me something else, and I grew up in Queens, New York. This relative said to me, "it's very important Howard when you're driving in the tri-state area that you don't speed too much because you can get a ticket and your rates will go up; but, if you are away somewhere, don't worry about it because New York will never find out if

you get a ticket somewhere else.” I put this in the back of my mind, not that I was a speed demon of course. Then in 2003 I was in Little Rock, Arkansas and I was pulled over by a county police officer for speeding in a residential neighborhood. And, sure enough, the points showed up on my license in the District of Columbia. I thought things must have changed since my relative told me this because all these States are somehow communicating with each other. This was a county police officer in Arkansas and this information went from his notebook to my driving record in the District of Columbia. The States, starting in 1960, had a driver license compact where they agreed to share information about drivers with each other, specifically moving violations. It was very slow in starting and kind of slowed down in the 70s and 80s and today about 45 States participate in it. If you think about it, it’s a pretty hard thing to do with 50 separate States, but it is all working.

I have another example from a very different walk of life, political campaigns. Political campaigns have to target voters and they have in their world what would be the equivalent of the high risk voter as opposed to the individual that always votes for the same party. It used to be they would run advertisements on television and they might geographically target them a little bit so an advertisement that is run in the D.C. area that’s run in the northern Virginia suburbs of D.C. would be different from advertisements run in southwest Virginia near the border of Tennessee as the voters would have different interests. Over time, they developed what we would call risk models. This is Federal and State parties working together across the country with thousands of candidates and every two years the system starts ad hoc. They look at magazine subscribers and they look at what we buy. The information is public, they mine data about all of us and they target specifically people with messages they think they want to hear and they try not to waste money on those of us who are going to vote for them anyway, or they try to motivate people to contribute money who have a history of doing so. They have sophisticated models and they all work together and it is a risk model and a system of cooperation among parties and candidates spread around the country.

A third example involves State and Federal law enforcement. Someone arrested by a State officer can find himself in a Federal court where State evidence and State and Federal experts are used. Also, if there is international involvement, information from an outside government is in the courtroom even if you were arrested on a country road somewhere and it all works together every day.

I give these examples to show again the absolute necessity of what we are doing in building on our mutual reliance and looking at risk in what we do to face the challenge. Our challenge is greater than the challenges I mentioned before, and these methods are working elsewhere and they are methods we have to use ourselves.

I want to provide a couple of my favorite quotes. I grew up in New York and when I was growing up Mario Cuomo was the Governor and Governor Cuomo said, “You campaign in poetry. You govern in prose.” The second quote is from a Supreme Court justice in the 1920’s who said, “A page of history is worth a volume of logic.” What do these two quotes say? Well they basically say that theory is great, but actually doing it is better. Because you can talk about the theory and you can talk about your poetry, but unless you have your prose and unless you have a record of doing it and you’re accountable, you’re just hot air. I want to talk a little bit about some things we have been working on

at FDA with States – far from perfect, but I think are steps in the right direction. One involved cantaloupes in Colorado in 2011. Many of you know about this and what happened, but just a little background for those of you who don't. In late August, the Colorado Department of Public Health and Environment received reports of a *Listeria monocytogenes* outbreak. CDC was notified and the State of Colorado worked with CDC, and then with the FDA, in investigating the outbreak. On September 10th, FDA and Colorado conducted a joint inspection of a firm called Jensen Farms. Four days later, Jensen Farms initiated a voluntary recall and FDA, Colorado, and the county worked together to conduct an environmental assessment. Afterwards, importantly, in December, FDA along with all 50 States conducted a hot wash or lookback at what had worked and what did not. Communication certainly was not perfect during the recall and earlier communications about the health problems could have been better, but we had a joint approach to the inspection and we jointly got a firm to recall and remove the public health risk as quickly as possible. I draw two points from this. One is something that is a linguistic aspiration and the other is a point of continual improvement that we need to have. The linguistic aspiration is that it will be antiquated in years ahead to think of a Federal or State inspection or a Federal or State compliance or enforcement action or initiative as separate. In mutual reliance, we are aiming to build an integrated food safety system that would be a seamless web where we are identifying risks early on, where we are deciding what the best action is, who the best person is to take the action, and then we decide on the strategy later on to deal with the situation. If it's an enforcement tool, it might be a State one, it might be a Federal one, or it might be some combination of both. Someone giving this talk ten years from now would treat the notion of a bright line between a Federal inspection and enforcement action and State enforcement action as the equivalent of us talking about dial-up access to the internet. That would be an aspiration.

Another example is the State of Georgia in 2011. This involved filth in milled products in Georgia in January through April of 2011. Both FDA and the Georgia Department of Agriculture determined that a firm had objectionable conditions during inspections: filth, rodent activity, and the like. FDA in October conducted a re-inspection of the facility and documented objectionable conditions and requested that Georgia join the investigation. Two thousand (2000) bags of product were placed on hold under the Georgia "withhold from sale" provision and the firm agreed to a voluntarily seizure operation. FDA and Georgia conducted a joint settlement conference with the firm and the Georgia Department of Agriculture, and the firm entered into a consent agreement that included a monetary fine and the firm being placed on an accelerated inspection status to ensure resolution of objectionable conditions. Again, with this situation there were plenty of bumps in the road. There should have been earlier consultation that's again a theme that we have to work on as we build our mutual reliance. This approach should ultimately be how we choose to inspect and enforce in certain situations and it is something we should aspire to do much more often. In my old job in the Office of Enforcement, we would consider enforcement actions, and what I would say then and what I say now is that I don't care if it's a Federal enforcement action or a State enforcement action, because our measurement at FDA is not how many seizures, or injunctions, or letters, or whatever it is we do – it's how effectively we protect the public health. Sometimes it's accomplished by working with our partners, sometime by us, and sometimes it is input from a State to us or from us to a State. Sometimes it's a global product stopped from coming into the country, with us all sharing information. We don't get any awards, any of us, State or Federal, by simply increasing the numbers of

what we do in isolation. It would be quite possible for FDA itself or for a State to increase its number of enforcement actions. Increase those numbers, but at the same time the public health is being protected less because it might be that particular action is inefficient because the State or Federal government could have done it better. And while one of us was taking the less efficient step and wasting resources, we could have been using something else, the other part could have been doing it much more efficiently. We have to think that way not just as a matter of budget, but again as a matter of public health and the way we measure what we do. All of us in the room are collectively responsible for working to protect public health.

Another example is the apple sauce investigation initiated based on reports of illnesses in school children in Raleigh, North Carolina. Field examination of the product revealed damaged, leaking, and corroded cans. There was an investigation and North Carolina advised the FDA with information and contacted the Washington State Department of Agriculture. A rapid response team was activated, an investigation initiated at the manufacturer, a joint investigation conducted of the firm, and the investigation then continued with additional product samples collected and product embargoes issued. The situation involved school children in North Carolina, product in Washington State, and the Federal government. We, the two States and the Federal government, used an incident command system to make our communications better. FDA and Washington State are working together on the ongoing compliance efforts with the firm to follow-up on this event. Again, some lessons here are not just communication, but organizational. As we will increasingly have outbreaks and public health challenges that cross borders of States and indeed countries, it's important not just that we communicate, but that we organize ourselves. It's one thing to have a phone call or email, but we actually need to put together a joint plan, or rapid response team, or command system so that we are functioning like a centipede whose legs are all moving together.

I wanted to mention a couple of other programmatic areas of advancement that FDA is working on in building our mutual reliance. One was the conference training that many of you were at in Kansas City in March 2012, which was the first annual *Manufactured Foods Regulatory Program Standards* (MFRPS) training. I don't need to tell this audience how important MFRPS is to food safety and to a nationally integrated food safety system. The training marked the official formation of the manufactured food regulatory program alliance (MFRPA), which will facilitate long-term improvements to our national food safety system and strengthen Federal-State collaboration. In the feed area, the animal feed regulatory program standards have been completed and are in the initial process of review at FDA. Our first volume of the rapid response team (RRT) manual of best practices is in the final stages of vetting, editing, and clearance and it should be ready to be shared publicly soon. These again are a few efforts at building our mutual reliance, building structures to make it organized, and then hopefully learning from each other. We at FDA are tasking ourselves to work much more often with ourselves and the States in hot washes, which I mentioned earlier.

Albert Einstein defined insanity as "doing the same thing over and over again and expecting different results." We have incredibly important jobs where unpredictable situations can arise. However, what we do is predictable in a certain sense, which is that there will be outbreaks, they will cross borders, and they will increasingly involve products that started off from abroad. As we work through these and some of the examples I gave earlier, we have to learn from each one so that we are not having the

same conversation in the future. We should be looking at some of these outbreaks that arise and say to ourselves that we've seen this movie before, the ending was pretty good, but not great, and let's make the sequel better. We accomplish this by conducting hot washes and learning from each other.

I want to close with one other important part of what we are doing, which is accountability. Consumers, industry, government, and the public at large expect a lot of us as they should. The Food Safety Modernization Act (FSMA) gave the collective us additional tools to let us investigate better, let us work better at the border, and let us do enforcement and compliance better. FDA is working with the States and there are contracts and grants that FDA works with States on. And with all of this additional responsibility, with the additional money, there quite rightly is additional accountability and there will always be additional questions asked of us. How are we using this additional authority? How are we using this money? If we are not using it wisely, we are not going to get new authority, we are not going to get the money, and we are going to be in a far worse situation than we are now. So when I say that I have aspirations of what our system should be, I'm also saying it's a necessity that we build mutual reliance, that we learn not only what we do right, but what we do wrong, and that we hold ourselves collectively accountable for what we do well and what we don't do well. Thank you very much for your time and I appreciate the hospitality.

USDA Keynote
Elisabeth A. Hagen, M.D., Under Secretary for Food Safety
U.S. Department of Agriculture
AFDO 116th Annual Educational Conference
Providence, RI -- June 4, 2012

(transcribed)

Good morning, everybody, and thank you so much for having me. We've been looking for an opportunity to talk to this group for some time, and I'm really glad that we were able to make it work this year. I have the chance to meet with folks in your leadership fairly regularly. I will tell you that Oscar represents you all very, very well. And it's good to be here with the whole group of you.

This is a really great time to be working in food safety. There are a lot of important changes and improvements underway, as my colleague just told you about. A lot of them are happening at FDA on major scale. But we're pretty busy at USDA as well, and we're enjoying, I think, a higher level of collaboration than we've provably ever have with FDA over the last couple of years. As you know, President Obama made food safety a priority of the administration really from the very start. He made it clear to those of us who work in the administration on food safety that, given the size and the scale of the public health threat, he expected that we would have new and innovative policies that would be designed to actually make food safer than it's been before. And he also made it clear that we need to work together. So I would say, perhaps, more than any other audience I get to talk to, you all understand just how complicated the regulation of food safety is and just how many of us are working from how many different angles to make sure that food is as safe as possible. And, that when things go wrong, we're able to mitigate them as quickly as possible. So I'll talk a little about collaboration today because it is so important. And after all, if we're not sharing information and we're not collaborating, we're obviously missing an opportunity to protect consumers. And that's what this is all about. And it bears repeating over and over and over again that we're here to protect consumers. We're here to make sure that the food that people put on their tables is as safe as possible. The work we do is about real people and the impacts on those people and their families.

So when I came to this position almost 2 years ago now, I had the benefit of having worked in my agency for four years. And prior to that, I worked in private medical practice and academia with patients who were often sickened from the very organisms that I am now charged with keeping out of the food supply. And quite a few of them actually died from something that they ate. So these experiences that I had working in FSIS, the public health science office and working in medical practice really taught me a couple of key lessons. And the first of those is that nobody should lose a child, parent, spouse, friend, or anyone important in their lives to a contaminated hamburger, or a salad, or a cantaloupe, or name whatever you want to name. I think the second lesson that I learned is that, we can all agree, and we do all agree, I think, across agencies, professions, walks of life, political lines and parties, that what I just said is true. Nobody should ever lose somebody they care about to a contaminated meal. The third thing was that those of us who work in food safety really believe that our work matters. We

are all really committed to this. It's something we talk about at FSIS all the time. And we want to know that that work is going to lead to better results than it has in the past. And I realize that FSIS, as a public health agency, really owes it to the American public to find new and better ways of doing things, and to really make preventing foodborne illness a priority. So we all know the numbers: 48 million people are sickened every year. 127,000 hospitalized, and 3,000 die from foodborne illness – and all of it preventable. So what do we do about that? That's the question that we've been asking all along.

I am pleased to say that, at FSIS, we have made some real important progress against fighting foodborne illness, and I am delighted to be out talking in public to a group of people who care about food safety, today, on June 4, because June 4 is a big day for us. Today is the day we finally start testing for 6 non-O157 Shiga toxin-producing *E. coli* or STEC in beef products. This is a policy that has been a long time in the making, and it's the right thing to do. So at this time, starting today, any products that are produced today, or beyond, that test positive for any of these pathogens, cannot enter commerce and, if they do, they have to be recalled. This is the kind of action that consumers should expect from the agency that is charged with protecting them and is charged with protecting the beef supply from harm. So we've had previous success with similar policies. FSIS's zero tolerance policy for O157 in raw beef has led to or contributed to a dramatic decline in illnesses from this pathogen. Illnesses attributable to *E. coli* O157:H7 have decreased almost 50% during the time this has been considered to be an adulterant in beef products, and we collectively, as a nation, have been able to reach our Healthy People 2010 objective for this pathogen a year early actually.

There are important lessons that we can learn from some of the successes that we have had and that we can use to form our approach on other pathogens and other emerging threats, particularly on *Salmonella*. Of course, with *Salmonella*, we are dealing with something different. We've had to address it in a different way than *E. coli*. We have statutory constraints, and we have some technical obstacles in dealing with *Salmonella*, particularly in raw poultry, that we do not have with *E. coli*. But we also have an even bigger public health threat. We have over a million people in the United States being sickened by *Salmonella* every single year. In fact, it's responsible for more illnesses, hospitalizations, and deaths than any other bacterial pathogen that we track out there. So we have taken a number of steps to fight *Salmonella*. Actually, we have taken a lot of steps, and I'm going to try to keep my remarks short today so that we have some time for questions. So I'll just tell you about a couple things.

The first thing that we did was we instituted much tougher performance standards than we had before. We went from a 20% positive performance standard to a 7.5% positive performance standard last year, for broilers, that is. So this is a pretty strong standard. This is a tough standard. And this was a pretty significant move, and it wasn't welcomed by everybody. But I think we all know that we needed to be more aggressive than we were. And we expect that these stronger standards will help us reduce the number of salmonellosis by 20,000 cases per year, just by instituting these standards, once they are fully implemented.

Most recently, in January, we announced a proposal to modernize poultry slaughter inspection, and we believe that this is going to have a direct impact on human salmonellosis. As I said earlier, we owe it to the American public to do things better than we did yesterday - and certainly better than we did 50 or 60 years ago. And as the President and his Secretary made very clear, that may require big new fundamentally different ways of doing things than we have previously considered. So these are not the only steps we're going to take on *Salmonella* reduction, and that's certainly not the last step, but it's such a serious problem. We have to keep thinking of ways to combat it. We've made reducing *Salmonella* illnesses a huge part of our strategic plan. It's a very high priority goal. And, if you look at our strategic plan, you'll see it throughout the plan. Whether it's in communications, or it's in enforcement, or it's in laboratory methods development, reducing *Salmonella* is a huge priority for us. As we consider new interventions at the agency, it is increasingly more important to collaborate with FDA. And, as you know, FDA has also made *Salmonella* reduction a very significant priority and, together, we are the co-stewards of Healthy People 2020 objectives for foodborne pathogens.

I can't miss an opportunity to talk very briefly about PHIS, the Public Health Information System, when we talk about things that we've done in terms of big new ways to do things differently. The Public Health Information System has been something that has been in the making for a number of years, and it is a fundamental change in the way that we collect data, analyze data, and utilize data to inform first, and foremost, the daily work of our inspectors. But it also helps us in terms of analyzing long-term trends and policy development. This is a major change for us. We successfully implemented our domestic inspection module last year, and we just started our import inspection module at the end of May, and you'll see additional news coming out about the Public Health Information System in the months that come.

As I said in my introduction and I've said a couple of times, this is an exciting time to be a part of food safety, and we certainly have, across the board, I think, taken some major steps in the right direction. And it's been made very clear to us that we need to be looking top to bottom at the way that we do things and ask ourselves the hard questions about whether the way we are doing things is the best way they can be done. But we also recognized at USDA from the very beginning that incremental policy changes are very important as well. It's not all about the brand new roll-outs, the big flashy initiatives. There are some things that we need to do step wise that will add up to significant prevention measures. So we want to look at all the work that we do, and we want to take advantage of every opportunity that we have to prevent foodborne illness. As an example, as we continue to evaluate the ongoing results of our recalls and our inspection activities, we've learned that, while all plants certainly have HACCP plans, not all plants have them validated properly, or people have questions, particularly some of our small plant operators, about what validation means. Validation has always been a requirement under HACCP, but what does it mean, and what does the agency expect? This is an obvious problem, because HACCP is really the foundation of our pathogen reduction work. And so, proper validation of HACCP plans is a critical component to making our work successful. Again, our work successfully translates into people's safety at their dinner tables for meat and poultry. So it's really important that we're getting the big parts, the small parts and the in-between parts correct. Validation ensures that an establishment's HACCP plan will work in practice, not just in theory. Absent validation, a HACCP plan really can become little more than a piece of paper. And that

doesn't really do anything to protect consumers. We recently released guidance to assist plants with HACCP validation, and this guidance obviously advises them of steps they can take to make sure that their plans work as they are designed. This final product was kind of a long time in the making. It's gone through multiple iterations and multiple rounds of public comments, and I think the final product really reflects the public input from a broad array of stakeholders. In particular, it takes into account the concerns that were raised to us by small plant operators. This is meant to be guidance that helps the industry do the right thing so that consumers are protected. It was never meant to be overly burdensome or impose new regulations, and I think that we have been successful in putting out a product that really takes all of that into account.

Another area that we focused on is on trace-back. Under the new policy that we announced recently, we're going to be doing a couple of things. One, we will begin tracing product to the source much earlier than we have before. So we'll be acting on presumptive positives as opposed to confirmed positives. And we will be quickly focusing on the conditions in plants that lead to contamination or led to contamination regarding the sample that we're looking at, and we're going to be focusing a lot on what we call high event days. Trying to understand and to make sure that the industry understands what's going on during a high event period and what's being done. High event periods occur, and we understand that. What's important is what kind of decisions are being made around them and what's being done to make sure that those high event periods don't translate into higher risk for consumers. These changes are going to help us take action sooner in the event that we find contaminated product. They may allow us to keep contaminated product from ever entering commerce, ever entering our kitchens, ever ending up on our tables. And it just has us focused on, I think, a particularly important issue. As I just said, what's going on when something goes wrong, holding the industry accountable for explaining that to us, and demonstrating to us that they have the ability to make the right decisions when those kinds of things happen.

We've also taken a couple of other steps as directed by the 2008 Farm Bill to improve food safety. Establishments are now required to prepare and maintain recall procedures, and they are required to notify FSIS within 24 hours of discovering that contaminated product was shipped into commerce. Plants must also now document their HACCP plan reassessments. So, on their own, these policies may not seem like major changes, but each one of these actions has the potential to prevent an illness, to keep somebody out of the hospital. These are some of the small accomplishments that go a long way in terms of that big picture of keeping consumers safe.

So everything that I've mentioned really has to do with our work in establishments, in making sure that steps are being taken to prevent contamination in the slaughter and processing environment, sort of this box that we live in. And it makes sense that we focus our attention there, given what we know about pathogens and how they spread and the increased risk of the raw products that we deal with at FSIS. But it is increasingly clear, and I think clear to everybody in this room, that those risks are not confined to the slaughter and processing environment. At any point along the way, on the farm where animals are being raised, and all the way to the other end as food is being handled and prepared in restaurants and home kitchens, there is some degree of risk. So we have been continually looking at ways that we can make food safer - farm to table. We hear that phrase a lot. Farm to table safety, farm to table quality. All those

kinds of things. But we really mean it. We're really looking at what's the best way to look outside of our traditional confines to make sure that steps are being taken to produce food as safely as possible all along the way.

So let's talk a little bit about pre-harvest. We know that the conditions of animals, before they come to slaughter, will ultimately impact the degree and amount of risk that the rest of us have to handle the rest of the way through the system. FSIS does not have authority on the farm, nor are we looking for authority on the farm. We have our hands pretty full doing what we're doing. Our authority starts at the slaughter house store. But what do we do? We don't have authority there. It's not our core work, but yet everything we do, every policy that we put in place, every step that packers and processors take is impacted by what happens on the farm. But we start the conversation. We get people talking. We bring the right people together. And we talk about exactly what I'm saying right now. Everybody knows there are opportunities all along the way to do things differently than they've done them before. Getting scientists together with producers, talking about what's really feasible from a practicality standpoint, from an economic stand point. I think rightfully so, I think producers want food to be as safe as anybody else, but they want to know that what they may be asked to do is actually going to make food safer, and it's not just going to add cost and burden. So getting people together to talk about these things is the right thing to do. This past November, we co-sponsored a Pre-Harvest Food Safety Summit along with our partners at USDA who do work on the farm through animal inspection or through pre-harvest research on the farm. And we got that group together to talk with industry and academia and consumer advocacy groups about what are the things that can be done, and really focus again on this kind of feasibility, practicality aspect of it. Prior to that, we had put out some guidance on pre-harvest control of E. coli O157:H7 in cattle, which described the current state of research and also encouraged packers to look at what kinds of programs might be in place from the producers that they're buying from. So this document was never a new regulatory requirement. It wasn't new policy. But it's important nonetheless. And these kinds of conversations are important nonetheless. I think that this work that we're doing in pre-harvest, right now, we're focusing on cattle. I think in the coming months, you'll see us looking at poultry and talking about Samonella and Campylobacter, perhaps convening another meeting of the type we had. This kind of work is important, and it's the type of thing we can and should be doing where we have a stake and we don't have authority. So I am really encouraged by the discussions we've had so far. I think a lot of people at all points along the way, and industry in particular, recognize the possibilities of doing something very real for food safety. This is a place we will continue to explore, and we will continue to foster discussion and to connect and hook up the right people.

On the other side of that farm to fork continuum, we have the consumer. Industry has the obligation to produce safe food. We, in the government, have an obligation to make sure that that food is, in fact, produced safely and that what's supposed to be done is being done. But despite our best efforts, the system isn't perfect, and consumers can play an important role in reducing the risk of illness for themselves and for the people they feed: their families, their guests, and their friends. We're not really the food police. I think most of you in this room would classify as food police more so than us. We're not out there inspecting people's kitchens, nor do we intend to inspect their kitchens, just like we don't intend to inspect to their farms. But, we are going to do our best to make sure that consumers have the information they need to keep themselves

and their families safe. For example, the only way to know if meat, poultry or seafood is done to a proper temperature is to use a thermometer. We know from survey data that only ½ of American do this. It takes 5 seconds to stick your digital thermometer in there, and only ½ of Americans do this. That needs to change. And the way that we're trying to change those types of behaviors is through education. We've had a great effort on food safety education for years at FSIS. Lots of good stuff has been going on for a very long time: education in schools, fact sheets, videos, thing like this.

But last year we really stepped things up and partnered with the Ad Council to do a national multi-media campaign aimed at raising the awareness of foodborne illness, getting people to understand that 48,000,000 is a lot of people – that it's 1 in 6. That it's one in the group of people you have sitting around any given conference table at any given time, and that it can change your life forever. But to give them some real actionable behaviors that they can execute in their own homes because we don't want to scare people away from eating these wholesome products. And we are focused on our same four messages that we've always been focused on: clean, separate, cook and chill. These are simple things – making sure that your surfaces are clean, your hands are clean, that you cook food to a proper temperature, that you store it at a proper temperature. And partnering with the Ad Council has been really great because it gives us access to all kinds of markets and opportunities that we would not have had before. The Ad Council has done a lot of really memorable and notable campaigns that I think everyone is familiar with. There's Smokey the Bear, the Crash Test Dummies, This is Your Brain on Drugs, Autism Speaks – and all these kinds of things. So partnering with a group that's done these really notable campaigns has been very important for us and allowed us to develop relationships with the media that will outlast even the campaign itself. And we've been able to leverage the resources we've invested – a pretty modest investment by advertising standards – and really amplify our message quite a bit. In the first week alone, we were able to reach 20 million Americans when we launched the campaign at the end of last June, and we've done a lot of really neat things with them ever since then.

So, not only are we using mass media and traditional media to share our messages, but we are certainly taking advantage of new technologies and thinking about how people actually get their information these days. Just a couple months ago, we launched these state-specific Twitter feeds and the feedback so far has been really terrific on these – where we can get information out about recalls or about the things we send out ahead of natural disasters when we know a big storm is coming, safe food handling, things like that. People want to be able to subscribe to things that are local and important and impactful in the places that they live. We also developed a really robust question and answer database. "Ask Karen" has been a feature on our site for a number of years, and last year, we launched a mobile version of "Ask Karen" to make this question and answer database and live chat feature available to people the way that they live – on their smart phones. People aren't usually at their desktop computers when they have a food safety question. So this allows people to have "Ask Karen" with them. She's in the grocery store, she's at the grill, she's at the picnic. And they can ask questions 24 hours a day from a really well populated database, or they can live chat during the day as well. Summer has arrived and people are cooking outdoors more, and so we're focusing a lot on reminding people to be safe during that time, and we're following the traffic and we know that people have really picked up on this mobile "Ask Karen". That's something we're very excited about.

So that's a little bit about what we're doing. You guys are obviously always up to so much, and I want to make sure that I leave a little bit of time for questions that you might have. But I do want to say a big thank you to AFDO for the work that you are always doing. I know that we call on you very often for your expertise, and it's always appreciated. It's always a fruitful discussion and collaboration. In particular, I wanted to thank you for your assistance in putting together the HACCP-based guidance to meet variance requirements at retail. Very much appreciated. And I know that we're also working together on a small plant news guide book that's going to cover various exemptions to the Poultry Inspection Act and the Meat Inspection Act, such as the 20,000 bird limit and custom exempt and things like that. I think it makes a lot of sense. It will be a great and very useful product to put all those things in one place. And it really helps us achieve one of our big objectives – which is to continually strengthen our collaboration. So, again, thank you so much for your collaboration and assistance. I know that the good work this group does goes far beyond food safety, and I thank you for all of that and everything you are doing to protect public health.

DHS Keynote

**Dr. Alexander Garza, Secretary for Health Affairs and Chief Medical Officer
Department of Homeland Security
AFDO 116th Annual Educational Conference
Providence, RI -- June 5, 2012**

(transcribed)

Thanks everybody for inviting me here. I want to personally thank President Garrison, former President Klein and the rest of the AFDO leadership for inviting me to speak today. On behalf of Secretary Napolitano, I also want to thank everybody for all the work that you do across the nation to help protect our agriculture and food sector.

We all know that homeland security is really a shared effort. And, if there is one thing that the Department of Homeland Security does, it's a lot of coordination. We know that our success is really dependent upon your success on the ground. Thank you for all the hard work that you do.

I want to talk about three different topics. One is the threat spectrum, although I'm not going to spend a whole lot of time on that. The next is what we do at DHS in protecting the agriculture and food sector. And, the last is partnerships. And again, I want to emphasize that if DHS does any one thing, it's to coordinate and bring people together for a common goal.

So, this is just a little bit of background information about DHS in general and my office in specific. The DHS vision, as you can see here, is a safe, secure, resilient homeland, where America's interests, aspirations and way of life can thrive. And, underneath that is our office's mission, which is to provide health and medical expertise in support of the DHS mission to prepare for, respond to, and recover from all hazards impacting the nation's health security. And, when we refer to all hazards, we mean exactly that. It's all hazards that would impact the homeland. Included in that is the food and ag sector. I'll explain a bit further into my discussion how we do that.

We practice a "one health" approach. Our office is a bit unique in that we incorporate the human health, animal health and plant health into one office. I think that was a very good design for our office.

So, let me explain how we look at health and how our work is a bit different from the rest of the public health work that goes on within the federal government. Really, what we do is we look at health through a different prism than a lot of other organizations within the federal government, and our prism is national security.

We're a bit unique within the federal government. Clearly, we appreciate the need for and the importance of the provision of health care, but our goal is to protect the nation from health issues or to protect our national security from issues that can impact it from the health side.

We divide our office into two sections. The first section is what you would traditionally think of as the office of a chief medical officer. And, that is our Workforce Health and Medical Support Division. As many of you know, DHS has quite a large footprint, and we do a lot of different things. We secure the nation's borders. We protect its ports and maritime interests. We safeguard the nation's system of civil aviation. We protect the President and other heads of state. We respond to disasters, and do many other things. And so, all of those things require some sort of health and medical component. I tell my colleagues that health and medicine doesn't change from component to component. It's the execution of it that really changes. So what a secret service officer needs is very different from what a FEMA officer needs, and that's very different from what a TSA officer needs. And, we supply that health and medical advice for all of them.

I think the side of our office that you may be more interested in hearing about is our Health Threats Resilience work. And, that's what I describe as more of an outward facing function. So this is the part that deals a lot with the different threats that impact the nation. Included in that is our Food, Agriculture, and Veterinary Defense branch. John Sanders, a member of that branch, is here representing our office and participating in the meeting. We have about six veterinarians who work on all issues that can impact national security from a food, ag and vet standpoint. Another branch, which is related, is our Health Incident Surveillance branch, and that's a fancy title for enhanced biosurveillance or integrated biosurveillance, and I will talk a little bit more about that. Some of the other branches you may have heard of since we do work with our veterinarians in some of our other programs. One of them is our BioWatch Program, where we look for various pathogens of interest to the United States Government, within select cities across the nation, in an effort to provide early warning of a potential biological attack. BioWatch operates 24 hours a day, 365 days a year. Some of the other branches you may have come in contact with are Chemical Defense, and Planning and Exercises (which holds exercises around the country). Also, our State and Local Initiatives branch is our touch point with public health and law enforcement on the ground.

When we looked across the homeland security presidential directives, and all of our different policy papers, we identified four main priorities for homeland security. (You won't find this written in doctrine anywhere. It's sort of my view of the world.) We found that we could really boil it down to four things: 1) save lives, 2) ensure civil order and preserve government, 3) mitigate socio-economic impacts (I think that's where a huge part of the ag and vet sector comes into play.) And, 4) reduce the likelihood of another event occurring.

As many of you know, the Department of Homeland Security has what we call "critical infrastructure sectors" and, as you can see, the one highlighted is agriculture and food. As many of you also know, it's a huge sector of our economy. A huge portion of our gross domestic product depends upon the food and ag sector. We export about \$137 billion in agricultural products, so anything that would impact that would have an effect on our economic system and would also have an effect on the country. You can see where this would trickle down into a security problem as well. It's one of the few sectors that actually has a good record on exports beating imports. It's a big part of our economy, and it's something that needs to be protected.

Moving on from the role of my office, let's talk about the threat spectrum. With some of the work that we do, we have to explain what we mean by the threat spectrum, and how the different threats that are out there impact what we do every day. I think this would suggest to you that we still need to continue to focus on building a robust system for the defense of the food and ag sector. The way I explain it to many people is: It's not just one thing; it's many different things. And, it's not just one actor; it's many different actors. And, it's not just one cause; it's many different causes. And, that's what makes it such a challenging problem.

The threat spectrum goes from the naturally occurring pandemic (which we could be H5N1, H1N1, or any of these other viruses that emerge) to the accidental (from lab accidents to chemical spills), all the way to the intentional, including state-sponsored bioterrorism, or sabotage or attacks. On the far side of the threat spectrum, an intentional introduction of FMD into our cattle herds in the United States would have a devastating effect. And, you know, the terrorists are not dumb people. They realize that harming the United States doesn't necessarily have to mean killing people. It can mean economically bleeding us or making us work harder and divert attention away from other things. So although most of our attention at DHS is focused on the intentional side, we still have to be cognizant of the natural and the accidental. We still have to work across our different government agencies to make sure that all of these are protected. So, as we say, it's not just a one-agency effort. It has to be a whole-of-government effort, and I would say it has to be a whole-of-community effort as well. It can't just be about the federal government. It has to be about the entirety of the relevant sectors working towards these goals.

As I mentioned previously, H5N1 is, of course, something that is of concern to a lot of people in the federal government. As you know, it's called avian influenza for a reason – it's transported in birds. It's resulted in over 300 human deaths, but I think what you all would be interested in just as much is its effect on the poultry business. As you can imagine, any introduction of highly pathogenic avian influenza into the poultry business here would have a pretty devastating effect as well. Over 250 million birds have been culled in Southeast Asia as a result of H5N1. I'm pretty sure you all heard recently in the news about the different laboratories that have synthesized H5N1 to be much more transmissible. They do their experiments in ferrets because their respiratory system closely resembles the human respiratory system. And so there's a lot of discussion on whether this is a smart thing to do, first off, and then a lot of questions about security around the labs. So, would there be an accidental release of H5N1? And, what precautions do we have in place? Although there's a lot of debate on how serious of a threat this is, nonetheless, this is something that we have to think about and we have to prepare for. It's a potentially very dangerous virus. It's something that we have to make sure we have proper biosecurity measures in place for and, even if it wasn't affecting the human population, of course, it could decimate the poultry population, and that's an economic problem that we would have to deal with.

Next, I think everybody is probably very familiar with foot-and-mouth disease. We've been tracking foot-and-mouth around the world for quite some time. I know, USDA and FDA, it's always big on their list as well. Everybody's probably familiar with the outbreaks in South Korea in 2010 and 2011 – a very serious outbreak. They had to cull millions of animals and they had to deposit them in large pits. And, the problem with this is that some of the bodily fluids that leak out of these actually get into the water

system. So, again, it's not just the mere fact of the FMD, but it's also these second- and third-order effects. But even larger than that was the economic impact that it takes on these countries, where they're not able to export their beef or pork. South Korea had to destroy more than 30 percent of its domestic pig population, and 150,000 head of cattle. It's a devastating problem to the livestock industry. That fits along one of our priorities, as I mentioned earlier, with protecting the socio-economic aspects of the United States. Of course, this would have a huge impact on the economic conditions in the U.S. We just recently received a study from Iowa State University that was completed last fall and found that a disease outbreak in the U.S. pork and beef exports would lead to a loss of around 58,000 jobs, and an annual net loss revenue of about \$12.9 billion. And that's not even including the second- and third-order effects of processing centers and other individuals that would eventually lose their jobs just because the industry would be in such a downturn. So these are issues that we need to keep on the front burner, not necessarily because they impact human health, but because they can impact the economic stability of the country.

We always make sure we keep some plant stuff out there, too. This is a Kudzu bug. Everybody from the South understands the invasive species of the Kudzu vine, so then there's a Kudzu bug that's supposed to come in and eat the Kudzu, but what it does is it eats soybeans. So it's been steadily marching across the South, and it devastates soybean crops because it doesn't just eat the leaves and the stems, it actually goes down to the roots and destroys the plant from the ground up. It's been down in the southeast part of the country, and it's steadily moving its way up into the Midwest and, of course, in order to combat that, you have to use more pesticides, and then you have more drainage into the water and, as you can see, this causes more and more issues to come up. Be that as it may, again, the soybean crop is huge for the United States. Something like this would have a large economic impact on the United States.

Health threats take many forms. I just gave you a few examples. But consider that virtually all threats also have second- and third-order effects. Those are some of the things that we sometimes don't think about until we're actually in the throes of the fight. I try to remind people. I've done lectures about bio, chem, rad, nuke, and all these other issues, and when I was talking about rad/nuke, I was talking with a group down at the CDC about the Fukushima disaster. What I told them is that it wasn't that the reactor was actually a bad reactor, although it was a reactor issue, but rather a tectonic plate that shifted that caused an earthquake, that caused a tsunami, that flooded a town, that knocked out electricity, that caused the reactor to fail. And so it's not just the tsunami, it's the second- and third-order effects that we have to think about going down the line in order to avoid those disasters. Of course, the tsunami did a huge amount of damage, but the biggest impact to the United States, or the one that was most visible to the most people, was the radiation problem from the failed reactor. And so it's always those second- and third-order effects that impact us the most. To protect our homeland, we have to be mindful of those effects as well to protect our critical infrastructure from a lot of these so called once-in-a-hundred-years disasters.

How many people saw the movie Contagion? So I think everybody understands the plotline: an emerging infectious disease, no vaccine, spreads like wildfire, a lot of people get sick and die. There's this interesting scene in the film. I was giving another talk, and I was on the stage with the screenwriter of Contagion, who's from Minnesota by the way, and he said – just off topic – they asked him why he chose Minnesota, and he said,

“because that’s where I grew up, and I didn’t like the town that I lived next to, so that’s where I started the virus,” so if you’re from that town where it started, that’s why. Be that as it may, I was giving him a little bit of trouble on stage, because there’s the scene where the whole town is burning, and the hero and his daughter are going into the grocery store to try to find some food or something like that, and he’s telling her not to touch anything. And she’s like, “Dad, how come the buildings are on fire and there’s no firemen?” Well, the firemen are too afraid to show up to work. It shows that the airports are completely deserted, there’s no police, anything like that. And so I said, “But miraculously, the cell phone towers still worked. How did that happen? It’s not like cell phone workers just have this super immune system and can always go to work.” And, I can tell you, even in the position that I sit in, sometimes our cell service goes down for periods of time. But the point is that critical infrastructure is important! It can’t just be taken for granted, and it gets impacted by these events that occur, and we need to be thinking about those impacts as we’re going down the line. Or as I told him, it’s not really a disaster until your Blackberry quits working.

So our role in protecting the ag and food sector – and when I say “our,” I’m not just talking about the Office of Health Affairs, I’m talking about DHS in general – is pretty broad, and we work a lot with other agencies. It’s not solely a DHS effort. It’s really a combined effort of the federal family. In recognizing the importance of the ag and food sector, Presidential Directive #9, which I’m sure a lot of you are familiar with, was signed into law in 2004. It calls for the protection of the food and ag sector as a matter of national security. It set forth a lot of policies and procedures to guard against terrorist attacks, major disasters, and other emergencies. As with many things within the Homeland Security Presidential Directives, now the Presidential Policy Directives, it’s actually not just one agency; it’s a multitude of agencies involved in these processes and in this planning. DHS works with HHS, primarily FDA, the Department of the Interior, DOJ, EPA, and the Department of Agriculture. Many different people are involved in coming up with these plans and policies. With that said, we also have to work with our partners at the state and local level, because nothing can be executed without partners on the ground.

With respect to responsibilities, DHS is either the lead or co-lead in four areas: awareness and warning; mitigation; response planning and recovery; and research & development. Let me walk through a couple of the programs that we have that may be of interest to you, and may be something that you would like to be involved in. As many of you are aware, my office manages the National Biosurveillance Integration Center. The key word in that is “integration.” One of my pet peeves, quite frankly, is the word “bio-surveillance,” because it seems to be an all-encompassing word now that just goes outside of “bio.” It originally started in tracking flu or venereal disease, but now it encompasses such a wide area of information that biosurveillance is almost a misnomer now. But the key of what we try to do is not necessarily the biosurveillance, since we don’t have workers that go out and collect statistics on flu, or statistics on plant or animal disease. But really what we try to do is integrate information to get a global picture. To bring that information together to say this is what’s going on in the world, and this is how it’s impacting one sector or another. And so we follow things like food-borne outbreaks. We follow things such as FMD, and there are a couple of other issues that we track internally at DHS that are of importance to national security. But really the key is the integration. It facilitates the sharing of biosurveillance information, and it’s really the integration part that produces a shared picture for everybody. So we’ve

developed a couple of different tools such as the Biological Common Operating Picture or the BCOP. Maybe some of you have seen this. We're starting to pilot it with different states. It's shared amongst the federal partners, but we're starting to roll this out now to our state partners, and we have another picture that states can use as well. We're trying to develop this relationship where we can push and pull some data from the states to make it an even better common operating picture.

An example of what we've been doing recently is tracking the FMD outbreak in Egypt, Libya, and the Lebanese territories. It's an outbreak of a new strain, but it's always been living there. In Egypt alone, more than 80,000 animals have been culled, so this has reached the attention of the highest levels of government, and we've been briefing the White House quite frequently on what's been going on over in that section of the world and it's the ability to pull data from the State Department, USDA, FDA, multiple different sources and put it into one product for the national security staff that has really been advantageous for us. And we do have a very good working relationship with all of those different organizations.

Another thing that we do: Our State and Local Initiatives branch frequently reaches out to and works with a lot of state and local organizations, such as the Association of State and Territorial Health Officials, the National Association of City and County Health Officials, and organizations such as yours. This was one issue that they brought up when we were preparing this speech where I had no idea that this was going on at first. I thought they were pulling my leg – about fake health inspectors going out and inspecting restaurants. Has anybody heard of this? That's amazing. All right, so, what would implore somebody to be a fake health inspector? I thought it was, all right, maybe he's trying to get like a free pizza or something, but they were like no, they go there and call them up and try to involve them in these scams to sell them posters and some other things. I was like, this is ridiculous. Be that as it may, at AFDO's request, OHA arranged for a subject matter expert from our Colorado fusion center – we work a lot with our fusion centers to get public health people into that law enforcement community, because we think public health folks can really be a force multiplier with those organizations. So we brought in a gentleman who was a public health official from Colorado who worked in the fusion center and understood these scams that were going on and got him onto a teleconference with a lot of other states to explain to them how this whole scam was rolled out and what steps you can do to take care of it, but I thought that was amazing – somebody impersonating a food inspector.

Mitigation strategies: so now we're going to get into a little bit of work that's DHS-wide. Our colleagues at Customs and Border Protection operate the national Targeting Center and the Commercial Targeting and Analysis Center, and so it's a very sophisticated system. What it does is it sifts through advance manifests and passenger information to detect anomalies or red flags, and decide which passengers and cargo should be scrutinized at a port of entry, or in some cases, overseas. It really is a fantastic system that they have. But I think what makes it even more unique is that the FDA's prior notice center is co-located with it, and they work together, hand-in-hand, to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This act requires all foreign facilities that manufacture or process food for consumption in the U.S. to register with the FDA, and it also requires advanced notice of the imported food shipments. So CBP is actively involved in inspecting food.

At Customs and Border Protection, we have 2400 agents that sift through the cargo coming in to make sure that there are no threats to the agricultural system of the United States. They work with APHIS and FSIS, the FDA, the Consumer Product Safety Commission, as well as our immigrations and customs enforcement. As I said, over 2400 agricultural specialists prevent the entry of harmful agriculture and biological materials, pests and disease from coming into the United States. CBP also has some really cute dogs that perform a remarkable mission. This is one of them. She's a working dog, and she's another line of defense against food and plants that could have an effect on American agriculture, and she's trained to search for illegal foods stowed in luggage arriving from international flights. So we lull them to sleep with a cute dog, and then we nail 'em when she tags on something.

I'm going run through a couple of our other programs. NPPD does a fantastic job as well working with the ag and food sector. Through their regional resiliency assessment program, they reduce the nation's vulnerability to natural and manmade threats by evaluating critical infrastructure on a regional level, and coordinating protection efforts to enhance resiliency of the surrounding communities in geographic regions. They've done a couple of different projects around the country. They recently did an assessment of the beef industry in Texas, and the dairy industry in California. These assessments are being combined with regional analyses of surrounding infrastructure to reduce vulnerabilities to all threats. In addition, FEMA's National Preparedness Directorate has funded and managed stakeholder education, including training and materials related to the food and ag system.

I think some of you know this effort that's been going on, the FARM tool kit. Our own office (the Food, Ag and Veterinary defense branch) developed this tool. It's an online resource that's managed in partnership with the National Center for Food Protection and Defense. I think it's supposed to launch this summer. It helps states determine where they stand and what they need to work on with respect to their ag and food emergency response plans. The toolkit gives states lists of best practices, resources, training opportunities, and grants for which they may be eligible.

One other program within DHS that works very well is the DHS Science and Technology Directorate's three centers of excellence at the ag and food nexus: 1) The National Center for Food Protection and Defense at the University of Minnesota, 2) the National Center for Food, Animal and Zoonotic Animal Disease at Texas A&M, and 3) the National Center for Emerging and Zoonotic Animal Diseases at Kansas State University. Now I'm sure you've all been reading up on our efforts to develop a new zoonotic facility in Manhattan, Kansas. It's still very much the goal of the Department of Homeland Security to get that facility built.

Partnerships: As I said before, if DHS does any one thing, it's really to build partnerships. We don't have operatives out in other countries, but we look at intelligence. I don't have public health service officers out in the states, but we rely on the CDC and other agencies to bring us information. It's really to cull information together to look at it cohesively and how it impacts national security. I would say the way you all can get involved from the state and locals is through the programs that we have out here - whether it's with the Center of Excellence, whether you'd be interested in participating with some of our partners, or any of the other programs that we have out there - we would certainly welcome the input.

Last, but not least, let's talk about the dangers of products that could potentially be diseased or be a bio-weapon. We should use this as an analogy of how we look at food defense. You can't make a great cheeseburger without everything coming together, right? You can make up whatever you fit in this burger – DHS could be the bun, and state and locals could be the meat. The point being that there's a lot of work out there that needs to be done. There are a lot of different vectors that can impact the food and ag sector, and they are all things that we need to be working on together.

In closing, if you have any further questions, if there's something that I didn't explain correctly or if you just want to become more involved with some of the projects that we have going on, our web address is healthaffairs@dhs.gov. And I promise somebody mans that so you just won't get a bounce-back, and it'll get passed on to the folks that work in our office.

Thank you very much.

Health Canada Keynote
Paul Glover, Assistant Deputy Minister
Health Canada, Health Products and Food Branch
AFDO 116th Annual Educational Conference
Providence, RI -- June 5, 2012

(transcribed)

Good morning, everybody. I am very pleased to have the opportunity to be here and share with you a little bit about what we are doing at Health Canada, where we're moving forward, and how we're going to be doing that. I want to thank the organizers for the opportunity to come and share a little bit with you about our strategic direction and how we're moving forward. As you'll hear from me this morning, events like this are very important to international cooperation and they really play into the future that we see at Health Canada.

What I'm going to do over the next few minutes is take you on a little bit of a journey. What I'd like to do is set for you the context within which I find my organization operating in, what are some of the challenges that we're facing, the political and economic realities, and how, as the regulator, we're being asked to respond. It's interesting, as you heard, I was appointed last February to this post, a long-time regulator. And, when I arrived, one of the things that I found is that we run a number of different business lines. Some of them had fees that hadn't been updated in 14 years. One of the first things we did was updated our fees. That's great. We're very pleased about that, and we're able to work with our Parliament to make sure that we have fees that actually have an escalator so that we never get into that situation - when we've got fees that are 14 years out of date. That was a big part of it. Why do I say that? Because when you're living paycheck to paycheck, it's kind of difficult to operate. So we've stabilized our fees and fee structure, which is interesting. I'll come back to that point. That was part of the landscape when I arrived. The other thing - when I sat down with our political leaders, the same way that happens here with Peggy when she sits down with your political leaders -- they said, "We need you, Paul, to protect the health and safety of Canadians. That's your job. Job one. You make sure that you get that done." Okay, I got that. That's pretty straight forward. "But Paul, I want you to look around, and I would like you to recognize that we are in a difficult time. Governments around the world are struggling, and we want you to protect the health and safety of Canadians. They need safe food, safe drugs, safe medical devices. But we want you to do it for less money." Okay, I think I got that. Just updated those fees. And they were serious about that, and that was not, I think, unusual. I had the privilege of going to the heads of all the regulatory agencies around the world. We get together, and sort of say, so what's going on in your world? The conversation echoed -- pretty much everybody -- we've got a job to do. Safe food, safe drugs, safe devices. But can we do it for less money? And, if you think about the global economic context -- no real surprise there. Fiscal context is really important. So do that, but do it with less money was really part of it. How serious was the Canadian government on that? And again, we cost recover a lot, but not all, of what we do. We just took a budgetary reduction without any changes in service levels or fees of about 8.5%. That's what we are taking out of the organization over the next 3 years. They are very deliberate. The Canadian Government will balance

its books, on time, before 2016. That's their objective. They take that sort of thing very seriously. So the fiscal context as a regulator is really paramount.

At the same time, there are a number of very significant initiatives that were announced both domestically and internationally that I'll paint for you in about 40 or 50 seconds here. The first is the government felt that we had too much red tape, and they wanted to reduce red tape. So we had a red tape reduction initiative. Then they felt that, as regulators - not just me, but across government - we were really working too much with the large industry, and we had kind of forgotten how to interact with the small business. Let's make sure we're friendlier to small business - another initiative that was announced. A range of initiatives like that had come forward. The large one internationally was a regulatory cooperation initiative with the U.S., where we take a look at the regulatory systems that exist in both countries. We all have confidence in our regulatory systems. We move across the borders. We buy food. We buy medical devices. We buy drugs. And, we have confidence in those systems. But, we do it very differently. What are those differences? Why do they exist? And, what can we do to minimize those differences when they don't make sense, and improve cooperation as we move forward? So there's a large push on regulatory cooperation as it moves forward.

The other one that I think is probably the most significant in Canada that underscores the seriousness of my political masters is something called the one-for-one rule. The one-for-one rule, as a regulator, essentially says, for every one regulation we advance, we must remove a regulation equal to the burden that that creates on industry. Essentially they've capped the regulatory burden on the economy at where it is today. And for every regulation we advance, we must remove one equal to the burden that we've created. It means we really have to think hard about what we choose to do and where we choose to do it as it moves forward. But let's remember, I am to continue to protect the health and safety of my population in Canada; work with partners internationally; reduce red tape; be friendly to small business; be more international in what we're doing; and let's respect that one-for-one - choose very carefully. That was the political and economic environment that we were asked to operate within. That is still the case today.

What I would like to do, having painted that picture for you, is share with you how we intend to respond as an organization and what we're doing moving forward. I'm really going to focus on one particular element of this story in greater detail because, hopefully, I think you'll find it more interesting to you. We have three priorities, as most organizations do, and two foundational pieces. I'll talk about the two foundational pieces and the three priorities, but it is the third and last one that I think is most significant. But, we need to do all of them in order for you to have the context. As an organization responding to that context that I've laid out for you, we feel that there are two fundamental pieces that we cannot forget about. The first is that we are a science-based organization. We translate science into regulatory decisions, day in and day out, whether it's a product at the border, an inspector in a plant, a drug submission, a food additive that we're looking at. That's reams of data that we have to go through and make a decision - we place it either thumbs up or thumbs down, and it's a human being that does that. And, they do that based on science. So let's be true to our science foundations - the evidence base. We can't forget that. We're pretty good at that, frankly, and we think we've got a solid reputation; we're well published, reasonably well

respected. We don't want to forget that as we move forward. So staying true to the science – the evidence – that is our core competency.

The second, which is newer, is transparency. We have not been particularly good at transparency as an organization. Our website is too big, it's too hard to find. If you talk to the general public, if you look at the media lines I have to deal with, I think we create more questions for the media and general public. We feel we have to do a much better job at being far more transparent about what we do, how we do it, and how we make the decisions we make. Transparency will become an increasingly important piece of what we do moving forward at all levels, at all aspects. You'll see why that piece is, I believe, critical as we move forward. We think we do a pretty good job, frankly, on the transparency front with other regulators. We can share information around the world with trusted partners fairly easily. We can be transparent with our regulatory partners and with the industries we regulate. We think we can talk to them, and they can talk to us. But to the general public and to others, we're a little bit of a black box. It is a big mystery. We need to be clear about why did we approve that food additive; why did we not approve that drug; what are the conditions we're placing on the use of certain products; what are we finding; what are the adverse events; what did our inspections find in a particular plant as we move forward -- all of the things that, traditionally, industry says right now, most times, is CBI. I don't believe this, and we're going to move to make almost all of that available as we move forward. We look around the world to other jurisdictions, and we find that they've waived that CBI in other places. It's happening in other jurisdictions, so we think transparency is going to be critically important and, ultimately, we hope and believe a game changer to change the behaviors of the people that we work with. So those are the two foundational pieces.

The three priorities; the first two very quickly are people. As I said, it's the people that make those decisions that translate the science into regulatory decisions. And we need to make sure that we have the best and the brightest. I believe quite strongly that, as a regulator, we need to have people that are as good, or better, than the industries we regulate in order to be able to interact effectively with them. We need to understand the latest and the greatest science, be thinking about where that's going, and get to that slightly ahead of the industries we're regulating if we're going to be successful. Otherwise, we'll always be playing catch-up. So, investing in our people, in their training and, frankly, back to that 14 years, no-fee update -- the tools we give them. It's really important we give them modern, efficient tools as we move forward. We're not going to be shy about that as we move forward.

The second priority is operational excellence. We understand that we need to be more nimble. We can't take the years and years that we've done to do some of the reviews on some of the things that we deal with. We've had food additives in our systems for years, drugs in backlog. We need to be more operationally excellent as we move forward. There is a time clock ticking on everything we do. We need to understand that; we need to embrace it. And it's not about making decisions by the clock, but it's making sure that, in every step we take, we see the value-add, and if there isn't a value-add, eliminating it. It also means for us, in terms of operational excellence, demanding that of those we interact with. I'm still shocked – it bothers me to no end – to see a drug submission. First of all, we still have literally receiving bays where the 18-wheelers back-up and offload a drug submission. And it's 300-400 bankers' boxes of paper. We had paper on those boxes that we couldn't open because the mold and the moisture as

it was coming from the ship from Asia and became one brick. That's not operationally excellent. Why do we let the drug companies send us that stuff? We need to move into the modern age. And for those, we need to demand that they move with us. So things like that will be important. Just continuing on that example, before we submit a drug submission to a reviewer - and let's assume it's one that has 180 days as our performance time frame to get it done - 45 days are spent in screening to make sure the company sent us a document that could go to a reviewer. Forty-five out of 180 -- because we're not sure that they've dealt with us in an operationally efficient way before we send it. That is unacceptable as we move forward. Those are the sort of things. So it is both internally and externally as we move forward.

But the final piece that I want to share with you is what we think is most important and how we intend to become what we call a more modern, more efficient regulator moving forward, and that has three components to it that we believe will eventually transform the way we operate and do business. The first, and probably the most significant and of interest to you is, as a regulator, we need to move from being a domestic regulator - regulating domestic industries - to an international regulator. That's a pretty significant mind check. But frankly, the industries we regulate are all international right now. When we operate as a domestic regulator, we miss opportunities. We create confusion; we create red tape; we are not collaborating with our international partners. It doesn't make sense. We need to be more deliberately international in our approach right from the outset. So what does that look like? It is not - as you're seeing and hearing a lot - simply accepting the decisions from other jurisdictions. It's not even close. When we look at some of the products we have in backlog, generic reviews - most regulators around the world have generic drugs in backlog - take a look at that and say how many of our products have been approved by another jurisdiction, and how many of the products have we approved that are in someone else's backlog, and what can we do to help each other? To share review reports, to collaborate? What isn't in backlog that we can do together so that we have two sets of eyes on the same review to help improve it? In our situation, 40% of our backlog has been reviewed and approved by another jurisdiction, and so we're reaching out to those jurisdictions to say, "Can we work together?" And, "What's in your backlog that maybe we have approved and how can we collaborate?"

I'll tell you another little story to kind of put a point on it. I was speaking to a CEO of a company this past September and said, "How was your summer?" He said, "It wasn't too bad, Paul, but let me tell you what happened in July. Your organization came through. They inspected our plants. It was good. Here's how long it took us. Here's what it cost me, but it is the price of doing business. I understand that. You're a good partner. We don't mind." I said, "Well, thanks. I appreciate that". But let me tell you what happened in August. The FDA came through, did the exact same inspection we did. It cost them the exact same amount of time, exact same downtime interaction - one month apart. I don't think that is smart on either one of our parts, frankly, as we move forward. And I think there's an opportunity for us to integrate our inspections. I think it would be a whole lot more efficient to say, "I'm going in, in July, and FDA's going in, in August. Why don't you go in, in August, and we'll skip July, and we'll tell you the last time we were in, and why don't you follow-up on our observations while we were in, and why don't you share that report with us, and we'll go in next summer, and we'll pick up your report." And instead of going in the same regulator - not the same, but we're pretty close, we'll go to some other plant that maybe you were going to, and we'll

do that one for you, so that we can expand, maybe double our coverage. Wouldn't that make more sense as we move forward? It's not accepting the decisions of another jurisdiction. I can't go in front of my Parliament and say, "Why did you recall that food?" "Well, because they did." I think we have to have the science - the evidence. We have to make our own decisions. But certainly, benefiting from the exchange of work plans, whose going where, it's going to be really important. So being more international in what we do and how we do it is going to be really critical as we move forward.

We need to design systems too. Part of our modernization agenda is what we call proportionate oversight. I regulate everything from bandages to pacemakers. They're not the same. And, we have a very different system to regulate a bandage -- Just tell us where you're making it; if we get complaints, we'll send somebody in. Pacemaker -- that's a big full market review; we really need to take a look at that. How do we take that and apply that to all of the different business lines that we're in: foods, drugs, natural health products, devices? And, have we got proportionate oversight? So lower risk products -- maybe we want to turn the onus back on industry -- make them more responsible for it and put more emphasis on post-market surveillance, so we can put more of our emphasis on where it's needed: higher risk, higher uncertainty products, new products, novel products, new uses of products, as they move forward. That's going to be where we need to move forward, and that's how we're going to adjust our systems. It means where we have had historically things that had a 360 day review time, we're going to break that out and say our target isn't a minor improvement; they're monumental improvements. We want to be able to look at those things and, for those that don't take a lot of time, we want to go from 360 to maybe 10 days. Get most of those things in and out; they're not really worth our time. There will be a second bundle that we need to spend more time with -- let's take 30 to 60 days with those. Then, preserve that time that we need -- the 180 to 360 days -- for those highest uncertainty, highest risk products. Let's make sure that we're looking at those things and collaborating with our international partners in a way that makes sense. So that's some of the things that we're doing.

The final thing in our modernization agenda is, again, looking at the landscape of the issues that we have to deal with and recognizing what's coming at us, and the increasing complexity, is to minimize, frankly, the differences between the different regulatory schemes. We look at foods, devices, drugs, and increasingly, there are similarities in all of those things. Food wants to make health claims, wants to be more drug like. Drugs want to be a little bit more accessible, a little less accessible. We need a framework to understand that's where the market is going and be able to respond to that as it moves forward. Without that we have, in Canada, problems where people come to us to tell us what they are. They're not a food -- they're an over-the-counter. Or they're a natural health product. We call it reg shopping. They choose the stream they want to be in. We want to minimize those things so that, really, it doesn't matter what you are; it matters what risk you present in terms of the use of your product to the population and responding according to that.

We think if we can do those three things -- be more international in our approach, be more proportionate, and take a look at the range of regulatory systems and try to make sure they are more robust for the types of activities that are coming at us -- we will be more successful as we move forward. Going back to some of those other priorities -

that will allow us, we believe, to be more operationally excellent. It will allow our staff to focus on the things they care most about – those higher risk items that have a material impact on the populations we serve – keep us true to the science. And, frankly, if we are more transparent in doing all of those things, it will be easier for the population we serve to trust us, to understand what we're doing, and where we're going. And, it will be easier for us to work with our international partners as we move forward – to share reports, to collaborate, to cooperate as we move forward. We have mutual recognition agreements with some countries – we don't need them with all – as long as there is a willingness to collaborate, to cooperate, to exchange information – so that we can, rather than be duplicating the work, but sharing the work, working efficiently, we think that that will be an appropriate way to move forward. And put that in the context that I said at the beginning where we're under fiscal pressure to have the same level of protection but with less investment and resources – those sorts of things. Those sorts of activities can be done through better cooperation, rather than two countries inspecting the same plant, one goes somewhere and shares the report, someone goes somewhere else. We can be more efficient; we can collaborate better. And I think that that will be important. I will close by saying I also think that if we are collectively more transparent – not just sharing with each other, but with the public about what we found when we inspected that plant, what our operational observations were, the company's response to those things -- it will change behaviors of the companies. They do a little divide and conquer now. What did they find? What did Health Canada say? What did the FDA say? Those are minor differences. If we can focus on the big issues, that as regulators globally we're concerned about, and focus their attention on that, I think we will also be able to change their behavior as we move forward.

So that's a little bit about Health Canada, where we're moving, and certainly the importance of events like these. Again, I am very pleased to be here today to speak with you and to be able to facilitate the dialogue about how we can grow that cooperation. There's a lot of very formal work plans between the two countries through the regulatory cooperation council and others. We look forward to continuing to work with you and to being a part of that larger international community of regulators that I think is an example of what's attempting to be built. Thank you very much.

CFIA Keynote
Cameron Prince, Vice-President Inspection Modernization
Canadian Food Inspection Agency
AFDO 116th Annual Educational Conference
Providence, RI -- June 5, 2012

(transcribed)

Good morning, everyone. Thanks for the opportunity this morning to talk to you about some very important initiatives that are happening at the Canadian Food Inspection Agency (CFIA). It's definitely a very exciting time to be part of the CFIA and to be part of the whole community of food inspection around the world. It's great to be here today with like-minded folks that are interested in the kind of work we do and live every day at the CFIA. I was really struck by the words of both Paul Glover and Mike Taylor - how they resonate with what we're doing - the themes, the challenges, the initiatives. You'll hear many things in my presentation this morning that sound very similar to what you've heard already from our two previous speakers.

There really are three big initiatives right now at the CFIA. One of them that we are all very excited about is the possibility for new food legislation. The Canadian Government has made a strong commitment to food safety issues and has committed to tabling new food legislation in Parliament. It's very exciting for us, because it consolidates four different food acts that are quite different - different ages and different approaches - into *one* modern act. And that would be an excellent foundation for us as we move forward on inspection modernization.

Another initiative is regulatory modernization. Paul Mayers was here from the CFIA yesterday and spoke to that. That is looking at our whole suite of regulations and bringing those up-to-date, starting with some of the non-food areas in animal and plant health.

And the third initiative is inspection modernization, which is the part that I am going to focus on here today. Part of this is a new food inspection model. This piece is a significant change for the CFIA and I'm going to drill down and get into a bit more detail so that you can really understand where we are taking this new model.

Behind inspection modernization is, of course, knowing that Canada-U.S. cooperation is a very important: Mike Taylor mentioned that the CFIA is working with the Food and Drug Administration (FDA). There is also the Beyond The Borders initiative and the Regulatory Cooperation Council that were initiated by Canada's Prime Minister Stephen Harper and Barack Obama, President of the United States, that give us opportunities to streamline some areas in food that would facilitate trade and, at the same time, maintain high levels of food safety and consumer protection..

Inspection Modernization

It's interesting, when I talk about inspection modernization. I always use words like "new" and "improved" but, in many ways, this is not new at all. The Agency was created 15 years ago, so we are relatively young. We brought together Agriculture, Fisheries and

Oceans and Industry Canada – various departments that did food inspection – and brought them all under one roof. I was lucky to be part of the formative group that created the Agency. We always talked about having one food inspection program, but we haven't got there yet. We do have a very effective food inspection program, but it's siloed; it is very commodity-based.

This initiative is really looking at these silos with the intention of moving to a core food inspection program. I like to say that the stars have lined up; all of a sudden things seem to have gelled. In Canada's Budget 2011, the CFIA received \$100 million to facilitate inspection modernization. So we have the money to do this. We have looked at what's happening in the United States with the Food Safety Modernization Act (FSMA) – we are on the same voyage, with slight little differences in timeframe. These are exciting times for all of us.

We have great leadership as we strengthen our food inspection approach. Our Minister, Gerry Ritz, is very committed. The CFIA's President, George Da Pont, is strongly committed to this initiative and has been a key supporter. It's excellent to have that support.

We have looked at what's happening to industry around the world. We have seen with the Global Food Safety Initiative (GFSI), and other trends, that there is a greater interest on the part of industry for greater accountability. Internationally, industry has become a very big driver for food safety. That's an important factor for our work.

Another important piece to consider when thinking about inspection modernization is that the CFIA is losing experts, as are all organizations around the world, as people retire. We need to embrace this changing work force as an opportunity. At the CFIA we talk about the inspector of the future – it's those people who are being hired now who we're training now, who are going to work differently than we, including myself, did in the past.

So what is inspection modernization? What does the CFIA mean by that? We are starting on a very strong base: We have one of the very best food inspection systems in the world. The CFIA's is a science-based organization with a strong laboratory infrastructure. But, we need to strengthen the existing food inspection approach. We need to broaden our focus, move away from the traditional visual inspections, and move to a more modern and systemic approach to evaluating industry's preventive controls systems. Mike talked about risk-based resourcing. Exactly the same theme applies here: We need to be able to recognize emerging risk more quickly.

In Canada, we had a food-related tragedy in 2008 where 23 people died from a listeriosis outbreak. This has had a lasting impact on how we deal with food inspection in Canada. There was a report written about this occurrence called the Weatherill Report. In it, there were strong recommendations for investment in inspector training. That is an important part of the \$100 million we received and we have started on this part of the initiative. We are investing in inspectors, giving them better information and data systems and access to better science and laboratory capacity. This project is really about using investments wisely and looking at the existing human resources to make sure that we use those in the best way we can.

So why do we need to modernize inspection? The case for change, in this room, is fairly obvious: The globalization of the food supply; all of those food issues we hear about every day; consumer demands. These are driving us relentlessly and increasingly. The science of food safety and inspection is changing; there are new methods and new approaches.

While Canada has an excellent food inspection system, the issue with the Canadian system is that it is fragmented. We have a different inspection approach for dairy, eggs, meat, fish and others. This doesn't make much sense anymore. We're seeing, at the core of it all, risks are common. Protein is protein; risks are risks. We need to approach it that way fundamentally and then build on that with the expertise for each commodity. However, we will certainly need to continue to have commodity-specific subject matter experts,

The other driving factor is that trading partners are increasingly looking for evidence that the food system is working. So it's fine to say that we have a great food inspection program, but if you don't have the evidence to show it – the data, the surveillance information, the trends in foodborne illness – you don't have a solid story. The CFIA has most of the elements of the story, but we need better data to show the effectiveness of our system. As we move forward, trading partners and other authorities will be looking for that information.

So what has the CFIA done so far? We've made some progress over the last year. We have established a strong team that is managing the inspection modernization project. I am lucky to have the chance to do something I'm very passionate about – to lead this project. We report directly to the CFIA's President and the senior management committee on a regular basis. We also brief our Minister on a regular basis. As I have mentioned, there is strong support for this initiative. Over the winter of 2011/2012, we established a working group from across the Agency and developed a draft new food inspection model.

We also did what we call "listening sessions". These were not consultations, but we engaged industry, asking them:

- What do you think about the food inspection system?
- What are the strong points?
- What are the weak points?
- How do you see the future?
- What are your pressures?

This engagement was very successful – there was a lot of interest and great feedback from industry. We also did the same thing with the CFIA's front line staff asking them similar questions.

Part of the \$100 million is an initiative to provide an electronic certification and an electronic service delivery platform so we can connect electronically with industry. To help us, we've established an informal industry advisory group and we're finding that it is working very well to help us move forward.

We established an inspector focus group. We've had several meetings with that group, and it has been quite a revelation to hear their perspective. I find that the demand for change is more from the front line than anywhere else. These folks see every day what needs to be done to make a better food inspection system. We've learned a lot from these conversations. We've also met with consumers and we've also met with our unions. Our strategy from the very beginning was to be very open and transparent. The CFIA needs to make some change, and we want everyone's input.

We've updated some of our training and are looking at new training. We have begun work on a new information system, which is already showing benefits, and we've done some international benchmarking. We've done research on what is happening with modernization around the world. We know that the FDA has done similar work. We've engaged Dr. Bonnie Buntain, a professor at the University of Calgary, who spent a good part of her career at the United States Department of Agriculture (USDA) in the early days of Hazard Analysis Critical Control Point (HACCP). She has traveled to gather some excellent information about inspection modernization from around the world, including the United States and its modernization agenda. This information has been very helpful. It gives a global snapshot of where inspection modernization is going.

Improved Food Inspection Model

We are now focusing on the creation of an improved food inspection model. The model has implications across all elements of inspection modernization. We have distilled our various commodity programs to common elements, and those common elements from the draft model are:

1. Licensing
2. CFIA oversight – that is the frequency of inspection and the rigor of inspection
3. Inspection – how we actually do our inspections and verify compliance
4. Compliance and enforcement – how the CFIA does compliance and enforcement when we find non-compliance
5. System performance – how the CFIA validates the system

Licensing

Currently in the CFIA's licensing system, there are multiple licenses, depending on the commodity and what is being done with it. We're planning to move to one mandatory license for all companies that trade internationally or trade between provinces. A large percentage of the food industry in Canada, including food for import and domestic consumption, would require licensing. That's a big change for some industry as currently only certain sectors are licensed. A fundamental part of a license would be a mandatory preventive controls. We know that the FDA is working on licensing and we're examining this closely in the hopes that we have a similar approach. There would be conditions for all licenses and they would be centrally administered. Companies that operate across commodities, across borders, would have just one license with subsets for their various operations. So administratively, it will be more streamlined.

Level of Oversight

I think the next piece is extremely interesting, and it's the CFIA's approach to how we would do risk-based priority setting. We would set three levels of oversight for food operations: enhanced normal and reduced. It's pretty simple; we want to keep it simple. We will have a science-based group – based in our Science Branch – that will look at the risk parameters around each operation. Some would be low risk, with low-government intervention. But, in other cases, the level of risk could be high, and levels of inspection would be enhanced in those areas. This will give us an opportunity to adjust our resources across the food system and would enable us to have better science-based annual work plans, based on this risk.

Inspection

When it comes to inspection and compliance verification, we really are building on our current system. We have mandatory Hazard Analysis Critical Control Point (HACCP) in meat and fish; we have similar programs in our other commodities, and we have an inspection system which we call CVS (compliance verification system). We're not throwing those out the window. In a sense, mandatory HACCP will still be there, but it will be in a broader umbrella, so to speak. This is going to be significant change. It will mean a change for many of our inspectors – how they approach their work. They will be doing a systems audit for all foods now rather than just meat and fish. It will be based, again, on the preventive control program of each plant.

Compliance and Enforcement

Compliance and enforcement is really about being more consistent across commodities. Using some of the new tools we would achieve through a new food bill would give us quicker ways to deal with non-compliance – rather than prosecution, plant closures, or seizure. For the CFIA it really is about transparency – being more open about compliance and enforcement, and having a more integrated and consistent system.

System Performance

The final piece is systems validation and performance. This is really about the CFIA having the data to show internally that our quality management system is working; that we know that our inspectors are working effectively; that managers have information; that we can report to Canadians, to Parliament; and share information with trading partners to demonstrate that our system is working. With all of this we need to consider consumer acceptance. There is a perception – and we're all very familiar with this – when saying that industry is accountable that sometimes conjures up the image in consumers' minds that government is stepping back, and that really is not what this is about. We have to do the be clear in our messaging - that this is moving towards a much better food inspection system that gives greater assurances.

Things to Consider

A few things the CFIA is considering as we move forward with inspection modernization are:

- Our Human Resources systems will be challenged to meet all of these changes.

- We need to think about building new information systems and better tools for inspectors.
- A big factor is the impact on small business. There are a lot of small food plants in Canada and the U.S. How are they going to cope with this new world?
- Trading partner acceptance is key. None of this will happen if there isn't good trading partner acceptance.

Next Steps

The CFIA begins consultation on the draft improved food inspection model this coming fall and the revised model, based on the feedback we received, in the winter. We hope to have some consensus on new model by next spring. The work to implement the model will take place over the next three years. This is the window of opportunity we have been given in Budget 2011. It's an exciting project, and I was very happy to have had the opportunity to share it with you today.

Medical Devices in Canada

Christopher Rose, Manager, Medical Device Compliance Unit Health Canada

At the 115th Association of Food and Drugs Officials (AFDO) Annual Educational Conference, Health Canada presented information on the topic of medical devices in Canada and was asked for a submission to the AFDO Journal providing the information presented during the conference.

This paper will provide readers with information on:

- Requirements for the sale of medical devices in Canada, including device and establishment licensing
- Importation of medical devices into Canada
- Reporting of medical device problems (recall, voluntary and mandatory problem reporting)
- Safety surveillance and vigilance activities

INTRODUCTION

Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances. Health Canada's goal is for Canada to be among the countries with the healthiest people in the world.

To achieve this goal, Health Canada:

- Relies on high-quality scientific research as the basis for our work.
- Conducts ongoing consultations with Canadians to determine how to best meet their long-term health care needs.
- Communicates information about disease prevention to protect Canadians from avoidable risks.
- Encourages Canadians to take an active role in their health, such as increasing their level of physical activity and eating well.

Specific to medical devices, Health Canada reviews class II, III and IV medical devices to assess their safety, effectiveness and quality before being authorized for sale in Canada.

In Canada, the *Food and Drugs Act (Act)* allows for the establishment of regulations for food, drugs, medical devices, human semen for assisted conception, cosmetics and natural health products. It also grants Health Canada inspectors the power to enforce regulations.

Canada's *Medical Devices Regulations (Regulations)* came into effect in 1998 and contains some of the most stringent requirements in the world for authorization of medical devices. The *Regulations* regulate firms or individuals involved in manufacturing, advertising or selling of medical devices but does not regulate the use of devices by health care facilities.

REQUIREMENTS FOR THE SALE OF MEDICAL DEVICES IN CANADA

Classification and Licensing

Health Canada classifies medical devices into one of four risk classes. Class I medical devices represent the lowest risk where class IV medical devices represent the highest risk. Examples of medical devices:

- Class I – Toothbrushes, bandages and patient restraints
- Class II – Condoms and contact lenses
- Class III – Insulin infusion pump
- Class IV – Defibrillators, pacemakers and implantable drug pumps

Class II, III and IV medical devices require market authorization (device licence) issued by Health Canada in order to be imported and/or sold in Canada. The requirements for a device licence increase for each class of devices (Table 1). The requirements for the sale of class I medical devices are discussed in the section on establishment licences.

Device Class	II	III	IV
General Requirements Applicable to all Classes	Certificate from a CMDCAS (Canadian Medical Device Conformity Assessment System) recognized auditing organization The name of the device; The class of the device; The identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family; and The name and address of the manufacturer as it appears on the device label.		
Device Class	II	III	IV
Class Specific Requirements	A description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented; A list of the standards complied with in the manufacture of the device to satisfy the safety and effectiveness requirements; An attestation by a senior official of the manufacturer that the manufacturer has objective evidence to establish that the device	A description of the device and of the materials used in its manufacture and packaging; A description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented; A list of the countries other than Canada where the device has been sold, the total number of units sold in those countries,	A description of the device and of the materials used in its manufacture and packaging; A description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented; A list of the countries other than Canada where the device has been sold, the total number of units sold in those countries,

Device Class	II	III	IV
	<p>meets the safety and effectiveness requirements;</p> <p>An attestation by a senior official of the manufacturer that the device label meets the applicable labelling requirements of these <i>Regulations</i>; and</p> <p>In the case of a near patient <i>in vitro</i> diagnostic device, an attestation by a senior official of the manufacturer that investigational testing has been conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use.</p>	<p>and a summary of any reported problems with the device and any recalls of the device in those countries;</p> <p>A list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements;</p> <p>In the case of a device to be sold in a sterile condition, a description of the sterilization method used;</p> <p>A summary of all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, and the conclusions drawn from those studies by the manufacturer;</p> <p>A copy of the device label;</p> <p>In the case of a near patient <i>in vitro</i> diagnostic device, a summary of investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use; and</p> <p>A bibliography of all published reports dealing with the use, safety and</p>	<p>and a summary of any reported problems with the device and any recalls of the device in those countries;</p> <p>A risk assessment comprising an analysis and evaluation of the risks, and the risk reduction measures adopted to satisfy the safety and effectiveness requirements;</p> <p>A quality plan setting out the specific quality practices, resources and sequence of activities relevant to the device;</p> <p>The specifications of the materials used in the manufacture and packaging of the device;</p> <p>The manufacturing process of the device;</p> <p>A list of the standards complied with in the design and manufacture of the device to satisfy the safety and effectiveness requirements;</p> <p>Detailed information on all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, including (i) pre-clinical and clinical studies, (ii) process validation</p>

Device Class	II	III	IV
		effectiveness of the device.	<p>studies, (iii) if appropriate, software validation studies, and (iv) literature studies;</p> <p>In the case of a medical device other than an <i>in vitro</i> diagnostic device, manufactured from or incorporating animal or human tissue or their derivative, objective evidence of the biological safety of the device;</p> <p>In the case of a near patient <i>in vitro</i> diagnostic device, detailed information on investigational testing conducted on the device using human subjects representative of the intended users and under conditions similar to the conditions of use;</p> <p>A summary of the studies and the conclusions drawn from those studies by the manufacturer;</p> <p>A summary of the investigational testing and the conclusions drawn from that testing by the manufacturer;</p> <p>A bibliography of all published reports dealing with the use, safety and effectiveness of the device; and</p> <p>A copy of the device label.</p>

Table 1 – Medical device application requirements by device class.

In 2011 approximately 92% of medical device licenses issued were issued to manufacturers outside of Canada. A further breakdown of licences by company is provided in figure 1.

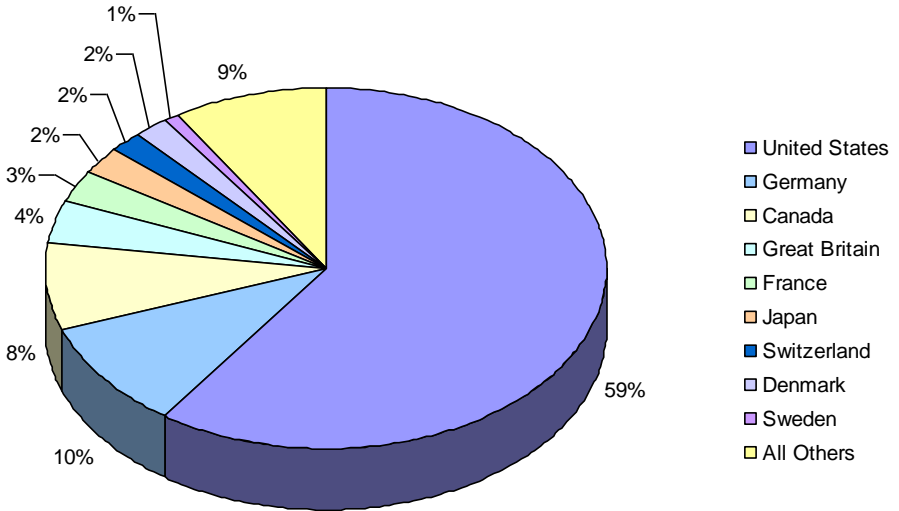


Figure 1 – Breakdown of percentage of licenses issued by country for 2011.

Changes to a device may require that a device licence amendment be filed; these may include a simple change such as a change to the device name or name and address of the manufacturer or more significant changes such as changes in design or instructions for use for the device. A manufacturer is required to submit a licence amendment to Health Canada for review and authorization once they have determined that the proposed change to a Class III or IV medical device is a significant change. Manufacturers may introduce the modified medical device, or components, for sale in Canada only upon receipt of an amended medical device licence from Health Canada.

The concept of significant change is linked to the principles of safety and effectiveness and the ability of a risk-based regulatory system to control the risk of medical devices offered for sale in Canada.

Canadian Medical Devices Conformity Assessment System (CMDCAS)

Health Canada incorporated a requirement for quality management systems in the 1998 *Medical Devices Regulations*. The *Regulations* require manufacturers to incorporate internationally based quality management systems requirements into the design process for class III and IV devices. The *Regulations* also require manufacturers to incorporate them into the manufacturing process for class II, III, and IV devices.

Health Canada developed the third-party auditing and registration system called CMDCAS. Its purpose is to establish and maintain confidence in, and control over, the process of third party auditing of medical device manufacturers respecting section 32 of the *Regulations*.

Health Canada, through the Standards Council of Canada, accredits international auditing organizations called Registrars to carry out third-party audits of quality management systems on its behalf. Each manufacturer must demonstrate to this accredited third-party registrar that it operates a quality management system that complies with the international standard ISO 13485:2003. Manufacturers are audited annually.

The Standards Council of Canada conducts annual oversight audits of all Registrars. Health Canada participates with the Standards Council of Canada in up to a quarter of the annual oversight audits.

Establishment Licences

Medical device establishment licenses (MDELs) are issued to a company (rather than a specific device) that allows them to import and/or sell a medical device in Canada. There are exceptions to this regulation as outlined in section 44 of the *Regulations*. The following are exempted from requiring an MDEL:

- A retailer;
- A healthcare facility;
- A manufacturer of Class II, III or IV medical devices that only sells:
 - medical devices for which they hold a valid licence, or
 - medical devices subject to Parts 2 and 3 of the *Regulations*;
- A manufacturer of a Class I medical devices who imports or distributes solely through a licensed establishment;
- A person solely selling medical devices subject to Parts 2 (custom-made devices and medical devices to be imported or sold for special access) and 3 (medical devices for investigational testing involving human subjects) of the *Regulations*; or
- A dispenser.

For manufacturers who are also involved in sales of other medical devices (for which they are not the manufacturer), the MDEL requirements are as follows:

- If they are involved in any distribution activities, such as sales to healthcare facilities, they are acting as a distributor for these other medical devices and require a MDEL for these activities.
- If they are solely selling these medical devices to consumers for their own use, and not for resale, the establishment is a retailer of these other medical devices and are exempt from the MDEL requirements.

Manufacturers of class I medical devices who sell their devices solely to individual members of the general public for their own use do not require a MDEL. As indicated above, retailers are exempt from holding a MDEL.

For persons who provide medical devices to consumers for their own use but are paid by a third party, such as a health insurer, the following applies:

- If the consumer becomes the owner of the medical device, the person is considered a retailer for this activity and does not require a MDEL.
- If the consumer does not become the owner of the medical device, because the third party retains ownership of the device (i.e. the third party retains the right to recover the device from a user and provide it to other users), the person providing the medical device to the third party is acting as a distributor and requires a MDEL.
- The person that sells to re-sellers is not a retailer.

IMPORTATION OF MEDICAL DEVICES

The majority of health products used and consumed within Canada are imported. The globalization of manufacturing and world trade has resulted in the increased importation of health products from countries with regulatory frameworks and enforcement policies that may differ from those in Canada. This globalization, combined with increasing movement of people and goods within the global community, make for more complex supply chains and, in turn, may pose an increased risk to the health and safety of Canadians.

Canada not only imports health products, but also exports a number of health products to other countries. As a responsible member of the global community, Canada must take all possible steps to export only those products which do not pose a risk to health and safety, and which are effective and of high quality.

It should be noted that Canadian law may classify and regulate various health products differently than other countries. These differences may result in either more or less stringent requirements. This should be taken into consideration before importing and exporting health products.

For the purposes of Health Canada's import and export policy:

- **Export:** includes, in addition to the sending or transporting of a health product abroad, the sale or advertising over the internet of a health product to a foreign jurisdiction.
- **Import:** the action of receiving or transporting health products across the Canadian border from outside Canada
- **Sale:** as per the *Food and Drugs Act*, sale includes to offer for sale, to expose for sale, and to have in possession for sale and distribution, whether or not the distribution is made for consideration.

Medical devices, when imported by an individual for their own personal use, are not regulated under the *Act* and/or the *Regulations*. However, all commercially imported medical devices must meet the requirements of the *Act* and/or the *Regulations*.

For commercial importation of medical devices into Canada, if the product is a Class II, III or IV medical device, then the product must have a medical device license issued by Health Canada; and if a Class I medical device, then the manufacturer must have a medical device establishment license (MDEL), or the Canadian importer must possess an MDEL.

REPORTING OF MEDICAL DEVICE PROBLEMS

In Canada there are three main types of reporting issues or problems with medical devices: voluntary reporting, mandatory reporting and recalls.

Voluntary Problem Reporting

Problem reporting is an essential element in the ongoing efforts of Health Canada to protect the health and safety of Canadians. Although only manufacturers and importers are required to report medical device problems under the mandatory reporting provisions of the *Regulations*, Health Canada encourages anyone purchasing, using or maintaining medical devices to report problems or concerns on a voluntary basis.

Generally, medical device problem reporting contributes to an increased level of medical device safety, effectiveness and quality.

A voluntary problem report is any account of an incident, complaint or concern involving a medical device forwarded to Health Canada at the discretion of the reporter. These reports include the following:

- Actual concerns, which have been detected during use or identified during testing prior to use;
- Concerns about the safety of a device or about its ability to perform as claimed;
- Deficiencies in the design of the device, defects arising from the manufacturing process, or deficiencies in labelling; or
- A contravention of regulatory requirements such as sale of a device without a device licence.

The submission of trade complaints by industry is captured under the voluntary reporting program.

Most post-market device problems are experienced in a healthcare facility by the actual user of the device. Because device users understand the procedures and conditions under which the problem occurred, the user's description and perspective of the nature of the problem is invaluable to Health Canada.

Mandatory Problem Reporting

Mandatory problem reporting is required under section 59(1) of the *Regulations* for any incident involving a medical device that is sold in Canada when the incident occurs either within or outside Canada:

- Relates to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labeling or in its directions for use; and
- Has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so if it were to recur.

- The manufacturer and importer are each required to make both a preliminary and a final mandatory report.

Manufacturers and importers are both required to report incidents regarding a medical device and within specified timeframes. If the incident has led to death or serious deterioration of health, the incident must be reported within 10 calendar days and, if the incident did not result in a death, but if it were to reoccur, could lead to death or serious deterioration of health, then the incident must be reported within 30 calendar days.

The requirement to report an incident that occurs outside Canada does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacturer to take corrective action.

Recalls

The definition of a recall in Canada is different than that of the U.S. FDA's. As defined in the *Medical Devices Regulations*, a recall is any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device:

- May be hazardous to health;
- May fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or
- May not meet the requirements of the Act or these *Regulations*.

The reporting requirements for recalls in Canada are outlined in sections 64 and 65 of the *Regulations* and recalls are required to be reported by manufacturers and importers. The requirement for reporting recalls described as "on or before" is satisfied by submitting a notice of recall within 3 business days of initiating a recall strategy. It is important to note that foreign manufacturers who submit recall reports should make these reports specific to Canada, including Canadian specific distribution information.

The recall reporting requirements described in Section 64 and 65 of the *Regulations* do not apply to retailers or health care facilities, such as hospital corporations who distribute devices among organizations that they control.

In addition the recall reporting requirements apply to manufacturers and importers of devices which they have sold in Canada.

Examples of recalls may include:

- An on-site correction of the medical device;
- An advisory concerning a problem or potential problem with instructions to work around the problem until an on-site correction can be implemented;
- The supply of revised labelling; or
- The supply of instructions to stop using the medical device and destroy remaining units in stock.

SAFETY SURVEILLANCE AND VIGILANCE ACTIVITIES

Health Canada has adopted a life-cycle approach in regulating health products including medical devices. This consists of regulatory interventions, where possible, in all stages of product development and use. Health Canada has a key responsibility for surveillance of the safety and effectiveness of medical devices once they are on the market. This objective is being achieved through key activities including: (1) information gathering, monitoring and processing; (2) signal detection and assessment; and (3) risk management and intervention.

Information Gathering, Monitoring and Processing

As discussed, problems associated with the use of medical devices are reported by manufacturers and importers (mandatory problem reporting) or by health care professionals and consumers (voluntary problem reporting). These reports are processed and assessed for completeness, and entered into a database for further review. Additional information concerning adverse events is gathered from various sources such as scientific and medical literature, other regulatory agencies and the media.

In its ongoing objective of improving an early detection of safety issues related to medical devices, Health Canada has established the Canadian Medical Devices Sentinel Network (CMDNet) pilot project. The project relies on a group of dedicated and trained representatives from acute and community-based healthcare facilities within Canada to report high quality data to the regulator about adverse events associated with medical devices. CMDNet provides a complementary data source to Health Canada in identifying emerging safety trends in the areas of medical devices and improve the safe use of medical devices.

Signal Detection and Assessment

Information sources, including those listed above, are gathered and assessed to better characterize a potential safety signal for medical devices. A safety signal is a suspicion that a connection exists between a health product and reported adverse events. Once identified, an assessment of the potential safety concern is conducted.

The signal assessment provides a consistent analytical approach, through the scientific/medical review of multiple data sources, in order to assess the linkage between the medical device and the adverse event. The objective of the review is to outline options and recommendations for risk management.

Risk Management and Intervention

In order to address a specific identified safety issue with a medical device, a risk management approach is defined, which may include interventions such as communicating risk information to hospitals, health care professionals and the public, labelling changes, or recommending that a product be removed from the market. Interventions are communicated broadly in the interests of transparency, increasing awareness and accountability.

SAFETY OF DEVICES IN CANADA

The safety of medical devices in Canada is a shared responsibility:

- The federal government is responsible for the regulatory framework, while the provinces and territories have responsibility for delivery of health care services.
- Manufacturers, importers and distributors are responsible for ensuring their practices comply with Canadian regulations.
- Health care professionals and patients have the responsibility to report problems with medical devices to Health Canada.
- Health Canada encourages health professionals and patients to report problems with medical devices to the Department.

HOW TO CONTACT US

For enquires related to:

- **Review of medical devices:** Contact the Medical Devices Bureau, Device Licensing Services Division by phone at 613-957-7285 or by email at device_licensing@hc-sc.gc.ca
- **Right to sell medical devices:** Contact the Medical Devices Bureau by phone at 613-946-6555 or 613-946-6553 or by email at License_Renewal@hc-sc.gc.ca
- **Medical device establishment licences:** Contact the Establishment Licensing Unit by phone at 613-954-6790 or by email at MDEL_questions_LEPIM@hc-sc.gc.ca
- **Importation and exportation of medical devices into/from Canada:** Contact the Border Integrity Unit by phone at 613-957-9994 or by email at BIU-UIF@hc-sc.gc.ca
- **Compliance and enforcement:** Contact the Medical Device Compliance Unit by phone at 613-954-6666 or by email at MDCU_UCIM@hc-sc.gc.ca
- **Surveillance and vigilance:** Contact the Marketed Health Products Directorate by phone at 613-954-6522 or by email at mhpd_dpssc.public@hc-sc.gc.ca

REFERENCES AND GUIDANCE DOCUMENTS

There are many documents which are available on the Health Canada website relevant to medical devices. The following is only a partial listing of some guidance documents which may be of assistance.

Medical Devices Regulations

- <http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/>

Pre-Market

- **Guidance for the Interpretation of Significant Change of a Medical Device:** http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/signchnng_modimportante-eng.php

- **Guidance Document - How to Complete the Application for a New Medical Device Licence:** http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_licapp_im_ld_demhom-eng.php
- **Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices:** http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/keyword_motscles2-eng.php

Post-Market

- **Guidance on Medical Device Compliance and Enforcement:** http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/gui_0073_tc-tm-eng.php
- **Guide to Recall of Medical Devices:** http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0054_recall-retrait-doc-eng.php
- **User Problem Reporting for Medical Devices:** http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-0060_prob-rpt_doc-eng.php
- **Guidance Document for Mandatory Problem Reporting for Medical Devices:** http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php
- **Import and Export Policy for Health Products under the *Food and Drugs Act* and its *Regulations*:** http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php

Temporary Foods in a Temporary Town

Richard Elloyan, REHS
Nevada State Health Division

I recall my first day as an Environmental Health Specialist; my new boss telling me that the best thing about my job, other than a steady paycheck, would be that there would no two days alike. Twenty one years later I can't swear that has been exactly true. However, I can say with a high degree of certainty that I've never had a day like a day at Burning Man. When was the last time you saw a guy in a pink tutu, boxer shorts, fishnet stockings, combat boots and a cowboy hat serving pancakes to a topless girl in a thong and knee high patent leather go-go boots? My guess is...not lately. However, that is exactly the attire you might find at a temporary food booth at Burning Man; and it hardly turns a head!

So, what is Burning Man? Not surprisingly I have been asked that question more times than I can count and, regardless of how I try, I cannot find a description that accurately conveys its propensity for being outlandish, spectacular, and miserable all at the same time. It is thousands of people thriving in the harshest landscape imaginable, alternating between temperature extremes of too hot, or too cold, and all the while wrapped in an alkali dust cloud that can bring all activity to a complete and sudden standstill. It is a head on collision between Alice Cooper and Cirque du Soleil...with 100 or so temporary food establishments and 1200 port-a-potties thrown in for fun. And, it goes 24/7 for eight straight days!

You can uncover almost everything you would want to know about the Burning Man experience by going on line and searching the endless number of web sites and the thousands of photographs that have been posted. You will see the location from the air, the thousands of motor homes, thousands of tents, the remoteness of the location and the most amazing display of art to be found anywhere in the world. It will probably leave you wondering why anyone on earth would haul a full-size pirate ship or two 18-wheelers welded together, or a 50-ton granite monolith to the middle of the desert just for the sake of artistic expression. Or, it may leave you ready to saddle up and head out to desert and experience it for yourself. One thing the web sites will not show you is what goes on behind the scenes. That is the curse, or blessing, of being an environmentalist. The better you are at doing your job, the less people hear about the job you do!

For a brief time, Black Rock City (the official name of the gathering location in the Black Rock Desert), with an estimated population of 60,000 attendees this year, will become one of the largest cities in Nevada and can certainly lay claim to being densest (in number of people per acre). What really makes this city unique is there are no services, no water supply, no sewer system, no grocery stores, no Starbucks or 7/11. What you will need to survive you must bring with you or you must barter for. The Nevada State Health Division, Environmental Health section, permits and regulates the temporary food establishments that operate on the playa (dry lake bed) for the duration of the event as well as the septic pumpers, sewage haulers and the 1200 port-a-potties that the Burning Man operators will provide this year.

The Nevada State Health Division's authority to permit and regulate at the Burning Man festival comes from the Nevada Administrative Code 444.547, Temporary Mass Gathering Regulations. A temporary mass gathering is defined as "an outdoor assembly of persons with an actual or reasonably anticipated daily attendance of not fewer than 500 persons that operates or may reasonably be expected to operate not less than 20 hours a day for more than 3 days and takes place at a location that lacks permanent facilities specifically intended for the type of assembly involved." Permit fees associated with a mass gathering are based on the population of the event on a daily basis with a maximum daily fee of \$1500 for greater than 10,000 people per day. Burning Man far exceeds 10,000 people per day and will probably reach its 60,000 person maximum daily event limit several days prior to the main event of the week when they burn "the man."

Staffing the event for its duration is a major logistical undertaking for a variety of reasons. The remoteness of the event, 120 miles from the nearest state office, does not allow for staff to commute and, even if that were possible, a huge number of man hours would be wasted just traveling back and forth. Permit fees generated from the mass gathering permit are used to provide temporary housing on the playa and help defray the cost of personnel. Burning Man is staffed only by Health Division employees that volunteer to be there. It is an extremely taxing environment, both physically and mentally, and requires a high degree of flexibility and self-confidence. In addition, the streets of Black Rock City are chaotic, crowded, and do not lend themselves to automobile traffic. All inspections inside the 5 square mile perimeter are done on bicycle. Bicycles are the chief mode of transport for all residents as driving in Black Rock City during the event is forbidden, with the exception of law enforcement and art cars. Needless to say, spending an entire day doing inspections via bicycle in high temperatures, high winds, and frequent white outs from blowing alkali does not appeal to everyone. In the past, safety concerns dictated that at least two inspectors be on the playa working together at all times but, as the event continues to grow, having gone from 20,000 attendees to 60,000 in a relatively short time, the number of staff at the event has also increased. All staff is required to bring with them everything they will need to do their job as well as survive in the elements. The laundry list of necessities, the emphasis being on food and water, contains enough items to see you safely across the Sahara. However, it must be kept in mind that there is no trip to Wal-Mart for sunscreen or toothpaste or any other forgotten items....you do without!

Perhaps doing inspections at Burning Man is not for everyone but, if there were ever a training ground for temporary food inspectors, this would be it. The majority of festivals, carnivals, and special events all have fairly predictable menus and, with the exception of the occasional deep fried pickle or whole turkey leg, it is going to be the usual tri-tip, hamburger, hotdog, corndog, cotton candy fest. Not so at Burning Man. This year, the Health Division has issued permits for camps serving: Miso soup, grilled cheese, schnitzel, spam kabobs, tofu and beans, ramen, solar hot dogs, spaghetti, cold cereal, bologna and bourbon shots, bread, tuna, and I'm sure a few surprises that even we don't know about. The current list of permitted temporary food establishments exceeds 130. There are two interesting things to note regarding these facilities. First, these establishments do not exist prior to the event, and all the materials used in their construction must be hauled in from off the playa, assembled on site, then torn down and hauled away after the event. These establishments vary in detail from the extremely primitive to complete reconstruction of a corner diner.

The second interesting thing to note is that no food from any establishment may be offered for sale...it must be given away. It may not be all that expensive to give away popcorn, but imagine the expense of serving pancakes to thousands of participants every morning for eight days. This alone offers a bit of insight to what makes this event so unusual. The very size of the city adds an additional level of frustration to inspectors as addresses on the playa are best described as relative. The city is laid out in concentric circles that radiate out in clock form from a central point. A street address may be described as 7:30 and Saturn, but there may be hundreds of tents and motor homes between that street and the next, with no indicators other than a long line at dinner time to hint at a food establishment's location.

As with any city of 60,000 inhabitants, there exists a massive, if mostly unseen, infrastructure that supports the event. Present on the Playa is a significant law enforcement contingent, a fire department, a medical facility, a Department of Mutant Vehicles, a pyrotechnics group, a building department, and an airport authority. All these agencies, including the Nevada State Health Division, meet daily to share information, concerns, and the schedule of upcoming events. Of particular interest to the inspectors is information provided by the medical team that might indicate an increase in patients exhibiting food borne illness symptoms.

The Burning Man event shows no signs of slowing down, and there has been discussion of increasing the event size to as many as 75,000 participants in the next few years. What was once seen as an event that was tolerated more than embraced is now seen as a major economic boon to the local economy and, these days, that carries considerable weight. The Nevada State Health Division has worked very hard to develop a level of trust and cooperation with Burning Man LLC. Each year the event presents new challenges and a host of opportunities for those teaching moments that promote public health and safety in our state, even in the remotest of locations. For more information on Burning Man, you can visit their website or contact me directly at Relloyan@health.nv.gov.

From the AFDO Archives (1939)

Common Food Infections

Ferdinand A. Korff, Director, Bureau of Food Control

Baltimore City Health Department, Baltimore, Maryland

Presented at Association Conference at Chicago, October, 1938

(reprint from AFDO Journal -- Volume III, Issue No. 2, April 1939)

Two outstanding groups of investigators have contributed much to our present knowledge of food infections, particularly those types of infections that cause human food poisoning excluding botulism. Savage and White¹ have recorded their findings in field investigative work and laboratory studies with organisms of the Salmonella group of bacteria. Dack and co-workers² have reported exhaustive studies on the ubiquitous staphylococci. Perhaps it is the studies on these two groups of organisms that have been responsible for their being found so frequently in foods that have been responsible for food poisoning outbreaks. It is the purpose of this report to review briefly the characteristics of the two groups of organisms so that the physician, the food inspector or food control official may obtain clues as to the cause of an outbreak of food poisoning and apply the necessary corrections to prevent recurrence of the outbreak without being delayed in awaiting bacteriological examination of the suspected foods. It should be noted here that the physician should always be consulted before an outbreak of food poisoning is investigated.

THE SALMONELLA GROUP

The Salmonella group of bacteria has been found following food poisoning investigations in protein-containing foods -- meats such as sausage, canned beef, potted meat, veal, roast pork, meat pies, mutton, poultry, chicken broth, chicken livers, chicken salad; dairy products such as milk, cheese, ice cream; sea food such as canned salmon; and eggs. The reservoir of infection has not been definitely ascertained. Persistent carriers are not believed to be the cause of spreading the infection. Passive carriers may be a causative agent. Animals may carry the infection particularly if they have been recently infected. Insects too may spread the organism to food by direct contact with infected material then to food. The period of incubation of the organisms on the food depends largely on the environmental conditions surrounding the food and with the type of food. The period of incubation or onset of the illness in the human appears to vary. Vomiting and abdominal pains appear from 6 to 24 hours depending upon the degree of infection of the food. There may be a delay of symptoms up to seventy-two hours. The symptoms are characterized by intense pains in the abdomen, vomiting, perspiration, diarrhea, high fever in some instances and prostration. Diarrhea persists for a period of time.

The various strains of organisms of the Salmonella group have been given specific names by investigators isolating such strains. The original Gaertner bacillus now known as Salmonella enteritidis was discovered by Gaertner in 1888. Other strains such as S. Aertrycke, S. Schottmulleri, S. Dar es Salaam, S. Newport, S. Stanley, S. Reading, S. Suipestifer and others been isolated at various times since. Still others will follow.

Dack and Davison³ state that members of this group appear to cause a specific infection of the gastro-intestinal tract without the formation of toxins in the food itself.

THE STAPHYLOCOCCI

The staphylococci have been found in recent years in moist food such as custards and custard fillings, chicken salad, Hollandaise sauce, ham, cheese, all of which are protein-containing food. The organisms seem to be ever-present. Having been found in suppurative infections food handlers so infected may be the cause of spreading the organisms to food. However, as the organisms are resistant to drying and low temperature, the ability to live, in a varied environment makes it difficult and well nigh impossible to ascertain the reservoir of the infection.

The period of incubation necessary for the growth of the organisms in food varies with the type of food infected and the environment. The period of incubation in the human is rather constant, usually within 2 to 4 hours. The symptoms include vomiting, diarrhea, pain in the abdomen, slight fever and weakness. Some of the organisms of this group, it is believed, secrete an enterotoxin during growth in the food, the specific toxin being thermo-stable and extremely potent. The toxin of some of the staphylococci secreted during growth in the blood stream, according to Science⁴ is more potent than the toxin of diphtheria or the tetanus germ. Grubb⁵ recapitulates the present status of the staphylococcus food poisoning problem and warns against drawing hasty conclusions even if the organism is found in food involved in an outbreak and even after toxin-producing powers of the organism isolated have been demonstrated. Being ever present, the organism may have infected the portion of the food obtained for analysis and not have been the original infecting bacteria.

It can be observed that there are four marked differences between the action of the two groups of organisms: (1) The Salmonella group causes the gastro-intestinal disturbance by producing an infection in the gastro-intestinal tract; some strains of the staphylococci, it is believed, secrete an enterotoxin, this toxin causing the illness; (2) the Salmonella type of food poisoning occurs after six hours and may delay its action up to twenty-four hours or even longer. Recovery is slow. The staphylococci cause the gastro-intestinal upset within four hours, rarely later than six hours. Recovery after the vomiting and diarrhea is rather rapid; (3) the Salmonella seem to have a preference for meat, meat products and similar food with high protein concentrations. The staphylococci appear to favor more moist or liquid protein-containing foods; (4) the chance of isolating the organisms of the Salmonella group from the feces of food poisoning victims seems to be greater than that with those of the staphylococci infected victims.

The outstanding difference of the effects of the two groups of organisms appears to be the time of onset of the illness. The staphylococci infections have as their onset period a shorter time as a rule than those of the Salmonellas.

PREVENTIVE MEASURES

Knowing the cause of the two types of most common food infections, some preventive measures should be expected. Cleanliness of equipment and personnel handling food may materially decrease the possibility of infection of food with organisms of the Salmonella group. Animals and insects should be kept from food preparing and storage rooms in order to prevent the possibility of their carrying the infection to food. Scrupulous care should be taken by food handlers to prevent unclean hands from coming in contact with the food. In the case of the staphylococci, because of their ubiquitous nature, it is almost possible to assume that many foods may become infected with these organisms. It appears that some time must elapse and an almost ideal environment for growth of the organism exist before the organism becomes dangerous. Prompt and complete refrigeration of the food after preparation will no doubt delay the growth and formation of the toxin. After the toxin is formed refrigeration or reheating will not destroy it. Reheating custard pastries after the custard is filled into the pastry shell will destroy the organisms provided the custard in the shell is heated to 180 degrees Fahrenheit or above. Refrigeration of the finished pastry during the entire period until consumption is an additional safeguard. Leftover food presents a problem. Sliced cooked meats should be refrigerated and kept refrigerated for the entire period of time during storage in the food establishment and in the home. The practice of slicing large quantities of meat and placing the slices high layers in the refrigerated show case should be discouraged. The cold air of the refrigerator penetrates but slowly to the center of the slices of meat that have come in contact with slicing machine blades. Salads and sauces should be kept refrigerated adequately until used. The basic preventive measures to employ in combating both the Salmonella and staphylococci organisms to prevent food poisoning is refrigerate, refrigerate, and then REFRIGERATE.

No attempt has been made here to discuss other types of food infection such as botulism nor of the true infections where specific organisms cause specific diseases such as typhoid fever, dysentery, undulant fever, and other communicable diseases. No attempt is likewise made to discuss other types of causes of food poisoning due to chemical contamination of food, inherently poisonous plant and animal substances, parasitic infections, allergies or those illnesses resembling food poisoning caused by the inhalation of toxic gases or eating food under adverse environmental conditions. Each of these groups likewise has an onset time of illness that is more or less specific or other characteristics that may aid the field investigator or epidemiologist in obtaining a clue to the cause of the outbreak. These have been referred to in a previous paper read from this association.⁶

At present it appears that the two most common types of food infection causing food poisoning outbreaks are the Salmonella group and the Staphylococci group of bacteria. Each has a different method of attack upon the human. Both of these types of food infections can be prevented by strict adherence to the fundamentals of sanitation together with prompt and ample refrigeration of the food during the storage period.

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(reprint from AFDO Journal -- Volume III, Issue No. 2, April 1939)

MARIHUANA AND NARCOTIC INSPECTION. James J. Biggins, District Supervisor, Bureau of Narcotics, U. S. Treasury Department, Washington, D.C.

OPIUM AND DERIVATIVES

Opium and its derivatives have been known for centuries for their properties in relieving pain, but there seems to have been little or no addiction to narcotic drugs in this country until about the time of the Civil War. The first serious effort by this Government to prevent the spread of this habit was in 1909, when Congress passed the Opium Act which forbids the importation of smoking opium into the United States and declares any opium found prepared for smoking contraband. In January, 1914, a second law was passed placing a tax of \$300.00 a pound on the manufacture of smoking opium, and requires that any person who manufactured opium for smoking in this country, must post a bond with the Collector of Internal Revenues to the sum of \$100,000.00. This bond and the tax was of course prohibitive, and there were no lawful factories producing opium for smoking in the United States. On December 17, 1914, Congress passed the Harrison Narcotic Act. This is a revenue measure, and requires all persons dealing in narcotic drugs in any manner to register with the Collector of Internal Revenue on July first of each year. Importers, manufacturers, producers, and compounders must pay \$24.00 a year tax; wholesale dealers who are allowed to sell narcotics only in the original packages, which bear Internal Revenue stamps must pay \$12.00 a year special tax. Retail dealers must pay \$3.00 a year special tax. Retailers are allowed to sell narcotics only from the original stamped package and must only sell narcotic drugs on prescriptions from physicians, dentists, or veterinary surgeons, weighing out or counting out the amount called for on the prescription. Physicians, dentists, veterinary surgeons are also required to register annually with the Collector of Internal Revenue and pay a special tax of \$1.00 a year. They may under the law, prescribe or dispense narcotic drugs to their bona fide patients in the course of their professional practice except addicts.

Laboratories which use narcotics for experimental purposes only are required to register each year and pay a tax of \$1.00. In 1922, Congress passed the Narcotic Drugs Import and Export Act prohibiting the importation of any narcotic drug except crude opium and coca leaves, and restricting the amount of those crude drugs to the estimated needs of the medical profession. In 1924, Congress passed another act which forbids the manufacture of heroin in the United States. The only heroin which can lawfully be prepared, used, and sold in this country at the present time is that heroin which was lawfully in the country and manufactured before June 7, 1924.

The physician, dentist, or veterinary surgeon who purchases drugs to dispense without the use of a prescription must keep a dispensing record to account for all drugs purchased on his order forms, thus practically eliminating the diversion of large quantities of drugs by persons registered with the Collector of Internal Revenue and who are allowed under the law to deal in narcotics.

The largest problem of the enforcement of the narcotic laws today is the organized gangs of smugglers. The protection of the public against illicit traffic in narcotics is the concern of the United States Treasury Department. The Bureau of Narcotics, the Bureau of Customs, the U. S. Coast Guard, and the U. S. Public Health Service function co-operatively.

MARIHUANA

The use of Marihuana has spread through this country within the past 15 or 20 years. Known and used since Biblical times, it has only recently come into use in the U. S. In 1937, Congress passed the Marihuana Act to control the traffic in this drug. Similar to the Harrison Narcotic Act, it requires those dealing in Marihuana to register with the Collector of Internal Revenue, and to transfer Cannabis or Marihuana by the use of order forms and the payment of a transfer tax.

The enforcement of this law presented a new problem in that Marihuana or Cannabis sativa will grow in any county in the Union. The plant has long been used in the manufacture of hemp twine and the seeds as bird seed and in the manufacture of oils. Whereas the source of supply for other narcotic drugs is foreign countries, Marihuana is found growing wild along many of our back-roads and river banks in this country.

The narcotic traffic will be properly controlled, our people protected from its temptations and addicts set free from its grip only by the wholehearted cooperation of all law-abiding citizens, state, and local officials with the Bureau of Narcotics of the Treasury Department. F. A. K.

TOMATO PRODUCTS CONTROL. H. V. Darnell, Chief, Bureau of Food and Drugs, Indiana State Board of Health, Indianapolis, Indiana.

The 250 canneries in Indiana are inspected under the authority of the State Food and Drug Law and State Sanitary Food Law. The chief problem involved in the control of tomato products lies in the prevention of the use of tomato rot and non-infested fruit. Education of the canner to buy and use only sound, ripe fruit is of the greatest importance. The practice of buying canning tomatoes on the basis of U. S. grades with Federal-State inspection is being adopted by more and more canners each year. The importance of proper washing, sorting, and trimming of the tomatoes with effective equipment is stressed. If because of bad weather conditions or heavy infestation of the local crop of tomatoes, canning operations are stopped.

Authentic and representative samples of the product are obtained for microscopic analysis by the Howard method. Plants are encouraged to employ a microscopist for these examinations. Canners in Indiana who are progressive have realized the importance of maintaining clean, sanitary plants and co-operating with the control official. F. A. K.

THE ICE CREAM LAW OF MASSACHUSETTS. Hermann C. Lythgoe. Director, Division of Food and Drugs, Department of Public Health, Boston, Massachusetts.

In 1934, the ice cream industry felt it was necessary that certain changes be made in the Massachusetts ice cream law. A bill was filed and resulted in a repeal of the existing ice cream law and standards, and substituted a new law comprising fourteen sections and in addition, making certain necessary changes in six other laws. This law required licensing by local boards of health; out-of-state manufacturers obtain their licenses from State Departments of Health. A graded fee system was established, the various frozen products were defined and the power to draw regulations was delegated to the State Board of Health.

The bacterial count from the passage of the law to the present shows that one-quarter of the samples obtained have counts below an average of 4,000; one-quarter of the samples have counts on the average above 40,000, and about ninety-two per cent of the samples have counts below 100,000. F.A.K.

CARBONATED BEVERAGES. Harry Klueter, Chief Chemist, Department of Agriculture and Markets, Madison, Wisconsin. Presented at Meeting of Central States Food Officials, Indianapolis, November 28, 1938.

The growth of the bottling industry in the past twenty years was discussed. The need of definitions and standards for each of the various types of beverages -- the non-fruit and fruit type was brought out by the speaker who also indicated the danger of licensing laws which are for the purpose of excluding competition. Some of the proposed changes in the state beverage law were mentioned. S.V.D.

FILTHY CANDY. F. L. Wollard, Chief, Baltimore Station, Food and Drug Administration, Baltimore. Presented at Baltimore Conference, December 7, 1938.

Filthy candy may fall within the following categories:

- (1) Candy manufactured or re-manufactured from unfit material and shipped interstate.
- (2) Candy which was sound when shipped, but through improper storage or age has become contaminated in the dealer's possession.
- (3) Candy returned by dealers to the original manufacturer for credit, presumably to be destroyed but which may be re-manufactured.

In the case of products falling within the first and third classes, the stations have proceeded by factory inspection of manufacturers to determine the composition, process of manufacture, and labeling of the products; but more important, the type and quality of the raw material, and equally important, whether insanitary conditions or practices prevail at the plant that would affect the cleanliness of either the raw

materials or the finished product. During inspections, special attention was given to such raw materials as:

1. Shelled nuts
2. Shredded coconut
3. Glace, dried, and preserved fruits
4. Chocolate coatings used in "bar" goods and in centers for coated candies.

Deplorable insanitary conditions were noted in a number of the factories which would almost inevitably affect the wholesomeness of the output. The equipment was frequently found to receive little or no cleaning after close of the day's operations, with the result that filthy accumulations of candy material were found caked on the kettles, pans, trays, and the metal-covered tables; the floors, walls, and ceilings, in many cases, were caked or splattered with dirty candy material that apparently had been accumulating for months; flies were prevalent due to lack of proper screening; evidences of rodent infestation were noted; material contamination was found in lots of fruits, nuts and other materials, due to storage in uncovered bins, sacks, boxes, or barrels and lots of moldy or insect-infested materials were on hand, either received in that condition or caused by improper holding or storage. Attention was also given to the possibility of excessive lead contamination due to the use of equipment repainted with lead paint or repaired by soldering.

The investigation indicated that notwithstanding the reputation of the manufacturer, returned lots of candy will either be remade or sold to some other candy manufacturer or junk dealer as scrap goods. Moreover, since the returns of candy to manufacturers vary widely in condition, some being merely discolored or having developed a "bloom," other lots being moldy or wormy in varying degrees, the manufacturer must then make a decision as to what is fit and what is unfit; and our experience has shown that the manufacturer is likely to use materials which are in some degree unfit. In other words, the judgment as to what is fit and what is unfit for manufacture probably should not, in cases where we have knowledge of the returned goods, be left to the manufacturer but should be decided by a regulatory official.

In the investigation of filthy candy falling within the second classification, particular attention has been given to penny pieces sold to children in small stores located near school buildings, cheap lines of bulk goods, caramels, fudges, coated candies, and "bar" goods containing nuts, handled extensively by wholesale grocers, candy manufacturers, doing a jobbing business as a side line, cheap department stores, chain drug stores, candy jobbers, and wholesalers, and cigar stores.

Examination of the many samples collected has shown the candies to be contaminated with such forms of filth as mold, rodent excreta and hairs, insects and worms and fragments of same, and miscellaneous foreign matter, such as small pieces of wood, sawdust, cinders, coal, feathers, etc.

A real problem exists with respect to the manufacture and sale of filthy candy, requiring the development of a definite program of regulatory control on the part of State, City, and Federal Food Officials. S.V.D.

AFDO Publications

AFDO Regulatory Guidance for Best Practices: Cottage Foods Revised April 2012

INTRODUCTION

The popularity of farmers' markets has surged in recent years and, as a result, an increase in the desire of many individuals to establish a cottage food business. Locally-grown and produced food is becoming more prevalent today, but laws that govern these entities are non-uniform. Setting standards that preserve public health while still allowing for economic opportunity has become a difficult task for state and local officials.

This document provides guidance to government food safety regulatory officials for the oversight of cottage food operations and represents a consensus opinion of best practices and limitations on this somewhat controversial matter.

Note that the FDA Food Code; Section 3-201.11[B] states "Food prepared in a private home may not be used or offered for human consumption in a food establishment".

DEFINITIONS

- (1) "**Cottage food operation**" means a person who produces cottage food products only in the home kitchen of that person's primary domestic residence and only for sale directly to the consumer. A cottage food operation shall not operate as a food service establishment, retail food store, or wholesale food manufacturer.
- (2) "**Cottage food products**" means non-potentially hazardous baked goods, jams, jellies, and other non-potentially hazardous foods produced at a cottage food operation.
- (3) "**Domestic residence**" means a single-family dwelling or an area within a rental unit where a single person or family actually resides. A domestic residence does not include any group or communal residential setting within any type of structure, or outbuilding, shed, barn, or other similar structure.
- (4) "**Home kitchen**" means a kitchen designed and intended for use by the residents of a home but which is also used by a resident for the production of cottage food products. It may contain one or more stoves or ovens, which may be a double oven, designed for residential use. It shall not include commercial types of equipment typically used for large wholesale manufacturing.
- (5) "**Permitted area**" means the portion of a domestic residence housing a home kitchen where the preparation, packaging, storage, or handling of cottage food products occurs.
- (6) "**Potentially hazardous food (time/temperature control for safety food)**" means a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

PREREQUISITE REQUIREMENTS

- (1) All cottage food operations must be permitted annually by the regulatory authority on forms developed by that authority. The permit will identify a specific listing of the food products allowed to be produced by the cottage food operation.
- (2) Prior to permitting, the regulatory authority will examine the premises of the cottage food operation to determine it to be in substantial compliance with the requirements of this guidance document.
- (3) All cottage food operations permitted under this section must include a signed document attesting, by opting to become permitted, that the permitted cottage food operation expressly grants to the regulatory authority the right to enter the domestic residence housing the cottage food operation during normal business hours, or at other reasonable times, for the purposes of inspection including the collection of food samples.
- (4) A cottage food operation must comply with all applicable county and municipal laws and zoning ordinances that apply to conducting a business from one's home residence prior to permitting as a cottage food operation. Where required, the cottage food operation will provide written verification from a credible recognized source of the adequacy of their on-site wastewater system.
- (5) Any cottage food operation which has a private water supply must have the supply tested prior to permitting and at least annually thereafter and demonstrate through a written record of testing that the water supply is potable. The regulatory authority may require more frequent testing as deemed necessary.
- (6) Prior to permitting, the cottage food operation shall have attended and successfully completed a food safety training program that includes training in food processing and packaging, and that is recognized by the regulatory agency.

LIMITATIONS

- (1) The regulatory agency may set limitations of total annual gross sales for a cottage food operation. If gross sales exceed the maximum annual gross sales amount allowed, the cottage food operation must either obtain a food processing plant license or cease operations. The regulatory authority may request, in writing, documentation to verify the annual gross sales figure.
- (2) Products produced by a cottage food operation must be sold directly to the consumer. Direct sales at farmers' markets, craft fairs, and charitable organization functions are permitted. Sales by internet, mail or phone order, or consignment, and sales to grocery stores and restaurants or at wholesale are prohibited. A cottage food operation may not operate as a food service establishment, retail food store, or wholesale food manufacturer.
- (3) A cottage food operation may only produce those specific food products listed on their permit. This permit shall be displayed at farmers markets, craft fairs, and charitable organization functions where cottage foods are sold.

INSPECTION

- (1) The regulatory authority may inspect at any time and whenever the regulatory authority has reason to believe the cottage food operation is in violation of these requirements or is operating in an unsanitary manner.
- (2) The regulatory authority may also inspect the permitted area of a cottage food operation in response to a foodborne illness outbreak, consumer complaint, or other public health emergency.
- (3) When conducting an inspection, the regulatory authority shall, at a minimum, inspect for the following:
 - a. That the permitted cottage food operation understands that only those specific foods identified on the permit for the cottage food operation may be produced;
 - b. That the permitted cottage food operation understands that no person other than the permittee, or a person under the direct supervision of the permittee, may be engaged in the processing, preparing, packaging, or handling of any cottage food products or be in the home kitchen during the preparation, packaging, or handling of any cottage food products;
 - c. That no preparation, packaging, or handling of cottage food products is occurring in the home kitchen concurrent with any other domestic activities such as family meal preparation, dishwashing, clothes washing or ironing, kitchen cleaning, or guest entertainment;
 - d. That no infants or small children are in the home kitchen during the preparation, packaging, or handling of any cottage food products; pets shall be excluded from the home;
 - e. That only normal, non-commercial types of kitchen equipment and utensils are used to produce cottage food products;
 - f. That all food contact surfaces, equipment, and utensils used for the preparation, packaging, or handling of any cottage food products are washed, rinsed, and sanitized before each use;
 - g. That all food preparation and food and equipment storage areas are maintained free of rodents and insects; and
 - h. That all persons involved in the preparation and packaging of cottage food products:
 - (i) Are not going to work in the home kitchen when ill;
 - (ii) Wash their hands before any food preparation and food packaging activities; and
 - (iii) Avoid bare hand contact with ready-to-eat foods through the use of single-service gloves, bakery papers, tongs, or other utensils.

COTTAGE FOOD PRODUCTS

A cottage food operation is allowed to produce food items which do not require temperature control for safety. The following foods are examples of products that may be produced by a cottage food operation. Although not all-inclusive, it provides for most types of approved cottage food products:

- Loaf breads, rolls, biscuits
- Cakes including celebration cakes (birthday, anniversary, wedding)
- Pastries and cookies
- Candies and confections
- Fruit pies
- Jams, jellies and preserves
- Dried fruits
- Dry herbs, seasonings and mixtures
- Cereals, trail mixes and granola
- Coated or uncoated nuts
- Vinegar and flavored vinegars
- Popcorn, popcorn balls, cotton candy

A cottage food operation is not allowed to produce food items which require temperature control for safety. Other food items which present a food safety risk such as acidified foods, low-acid canned foods, garlic in oil, and fresh fruit or vegetable juices are also not allowed. The following foods are examples of products that may not be produced at a cottage food operation. Although not all-inclusive, it provides for most types of unapproved cottage food products:

- Fresh or dried meat or meat products including jerky
- Fresh or dried poultry or poultry products
- Canned fruits, vegetables, vegetable butters, salsas etc.
- Fish or shellfish products
- Canned pickled products such as corn relish, pickles, sauerkraut
- Raw seed sprouts
- Bakery goods which require any type of refrigeration such as cream, custard or meringue pies and cakes or pastries with cream cheese icings or fillings
- Tempered and/or molded chocolate or chocolate type products
- Milk and dairy products including hard, soft and cottage cheeses and yogurt
- Cut fresh fruits and/or vegetables
- Food products made from cut fresh fruits or vegetables
- Food products made with cooked vegetable products
- Garlic in oil mixtures
- Juices made from fresh fruits or vegetables
- Ice and/or ice products
- Barbeque sauces, ketchups and/or mustards
- Focaccia-style breads with vegetables and/or cheeses

Food Labeling

A cottage food operation may only sell cottage food products which are pre-packaged with a label affixed that contains the following information (printed in English):

- The name and address of the cottage food operation;
- The name of the cottage food product;
- The ingredients of the cottage food product, in descending order of predominance by weight;
- The net weight or net volume of the cottage food product;
- Allergen information as specified by federal labeling requirements;
- Nutritional labeling as specified by federal labeling requirements is required if any nutrient content claim, health claim, or other nutritional information is provided; and
- The following statement printed in at least 10-point type in a color that provides a clear contrast to the background label: "Made in a Cottage Food Operation that is not Subject to Routine Government Food Safety Inspection."

A label sample is shown below.

<p style="text-align: center;">MADE IN A COTTAGE FOOD OPERATION THAT IS NOT SUBJECT TO ROUTINE GOVERNMENT FOOD SAFETY INSPECTIONS</p> <p style="text-align: center;">Chocolate Chip Cookies</p> <p style="text-align: center;">Ashley Bryant 2550 Kingston Lane York, PA 17702</p> <p>Ingredients: Enriched flour (Wheat flour, niacin, reduced iron, thiamine, mononitrate, riboflavin and folic acid), butter (milk, salt), chocolate chips (sugar, chocolate liquor, cocoa butter), butterfat (milk), soy lecithin, walnuts, sugar, eggs, salt, artificial vanilla extract, baking soda.</p> <p>Contains: Wheat, eggs, milk, soy, walnuts</p> <p>Net Wt. 3 oz.</p>
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FREQUENTLY ASKED QUESTIONS

Is there a limit to how much I can sell as a Cottage Food producer?

Some states have limitations in the amount of money a Cottage Food operation may make annually per household and operators that may be needed to maintain sales records and provide them to the regulatory inspector, upon request.

What types of Cottage Foods can I produce in my home?

Specific products are listed in the guidance document.

Will I need to meet local zoning or other laws?

Yes. Cottage Food Operators should contact their local unit of government to determine if there are local regulations that will affect their business. Note that it is possible, even in a state with a Cottage Food Law, for a local city or town government to ban home food production.

Can I utilize commercial type equipment such as large rotary mixers in my cottage food operation?

No. Typically a private home is not equipped with sinks required to effectively wash, rinse, and sanitize large commercial equipment.

Does my equipment, stove and/or refrigerator need to be NSF (a food equipment evaluation group) approved?

No. As a Cottage Food operator, you are not required to meet NSF standards for your equipment used to manufacture Cottage Food products.

Do I need to have a DBA?

A DBA (Doing Business As) may be a requirement of your county or local municipality.

The farmers market where I want to sell my products says I need a food license, even though I am a Cottage Food business. Can the market require a license?

Yes. Even though an entity may meet the requirements of a Cottage Food Operation and be permitted, some farmers markets or other direct marketing venues may require vendors to have a food establishment license or to meet other requirements. Local policies enacted by farmers market boards and other local governing bodies are generally outside the scope of any Cottage Foods regulations.

Are there any special requirements regarding my home on-site well?

Yes. Only potable water from a properly constructed on-site well or municipal water system can be used. If a well is used, the well water should be tested, at least annually, for coliform bacteria and nitrates.

Water from wells with any of the following features should be avoided:

- Very shallow depth (< 25 ft)
- Producing cloudy water
- Located in below-ground pit
- Buried wellhead

- Missing cap or seal
- Opening around casing pipe
- Located in close proximity to septic system
- Dug well

A list of water testing laboratories may be available from the regulatory agency. Local Health Departments can provide consultation on drinking water quality and well construction.

Are there any concerns related to my home on-site wastewater (septic) system?

Depending on the nature and volume of the food products which will be manufactured for sale, there can be adverse effects to the existing system serving the home. For instance, adding significant bakery wastewater cannot only increase the total volume discharged, but may also result in the increase in the organic strength of the wastewater discharged to the drain field, leading to the possibility of accelerated system failure. The adequacy of the home system to handle additional wastewater loading should be evaluated by the local health department prior to initiating manufacturing. The health department can advise you if modifications to the existing system may be necessary.

Why are some products not allowed to be made and sold under the guidance document?

The Cottage Food guidance document allows food entrepreneurs to operate small food businesses and produce a variety of food products that are low risk from a food safety standpoint, if prepared properly in an unlicensed and uninspected kitchen, while protecting public health to the greatest extent possible. The allowable products list is based on the food safety risk level associated with certain types of food. People who operate a licensed and inspected food processing business have to meet certain requirements for training, food safety and handling. Since Cottage Food businesses are uninspected, it is necessary to limit food products allowed under the law to those that are considered low risk, or non-potentially hazardous.

Are pet treats covered in the guidance document?

No. The Cottage Food guidance document applies to human grade food only.

Can I produce and sell cooked vegetable products, like salsas, tomato sauces, spaghetti sauces, or focaccia bread with roasted vegetables?

No. Food products made with cooked vegetable products do not qualify under the Cottage Food guidance document. Manufacturers of cooked vegetable products like salsas and tomato sauces must meet significant federal and state training and licensing requirements. Cooked vegetables, whether fresh or canned, usually are made from a combination of low acid and acidified foods, and are considered a Potentially Hazardous Food. Cooked vegetables must be held either hot (above 135°F) or cold (below 41°F). They can't be stored at room temperature, which makes them ineligible for production in a cottage food operation.

Can I roast coffee beans in my home kitchen and sell them?

Yes. You can roast and sell whole bean coffee or ground coffee, as long as you meet all of the provisions of the Cottage Food guidance document (labeling, storage, etc.); however, since beverages are not allowed under the Cottage Food guidance document, you may not sell ready-made coffee.

Can I bake bread in a wood-fired oven?

Yes, as long as that oven is in your home kitchen.

Can I make and sell apple butter, pumpkin butter or other fruit butters?

No. Fruit butters have significantly less sugar than a traditional jam or jelly. It is the combination of acid, sugar, pectin and heat that assures the safety of jams/jellies. In fruit butters, the combination of sugar and pectin is not large enough to assure that the butter is safe. Additionally, with lower sugar and pectin levels, spoilage organisms are more likely to survive the cooking process, which would allow for a micro-environment to develop and allow for the growth of *Clostridium botulinum*.

Can I press and sell apple cider?

No. Apple cider is not a food allowed to be produced. Actually, no beverages are allowed to be produced under the Cottage Food guidance document.

Are honey and maple syrup covered under the guidance document?

No. Honey and maple syrup are not considered cottage foods, because state regulatory requirements and exemptions typically have some significant differences.

Can I make and sell dehydrated meat or poultry?

No. Meat and poultry are a potentially hazardous food and are not allowed under the Cottage Food guidance document exemptions.

I lease space in a retail building where I operate a small antique shop. As a Cottage Food baker, can I sell my own baked goods from my shop?

Yes, as long as they are labeled correctly and completely, and the label includes any allergens the product may contain. However, you can't sell other people's products (e.g., consignment) nor have other people sell your products (e.g., wholesalers).

Can I make and sell hard candies or lollipops?

Yes. Hard candies, lollipops and peppermint candies are allowed under the Cottage Food guidance document, as long as they are labeled correctly and completely, the label includes any allergens the product may contain, and all other provisions of the guidance are complied with.

Can I make and sell sweet breads, muffins or other baked goods made with fresh fruits and vegetables like zucchini, pumpkin, and strawberries?

Yes, as long as the fruits or vegetables are incorporated into the batter and properly baked, labeled and packaged. The baked goods may not be decorated or garnished with fresh fruits or vegetables.

Can I use homegrown fruits and vegetables in baked goods?

Yes. You should take care to thoroughly wash the homegrown produce and the fruits or vegetables must be incorporated into the batter and properly baked, labeled and packaged. The baked goods may not be decorated or garnished with fresh fruits or vegetables.

Can homegrown produce be canned and used for making baked goods, like sweet breads, at a later date?

No, but you can use commercially-canned products for baked goods, like canned pumpkin, cherry pie filling, etc. Most home-canned products are not approved for production under the Cottage Food Law, with the exception of jams and jellies.

Can I freeze homegrown produce and use it for making baked goods, like sweet breads, at a later date?

Yes, as long as the frozen fruits or vegetables are incorporated into the batter and properly baked, labeled and packaged. The baked goods may not be decorated or garnished with fresh or frozen fruits or vegetables.

Can I make and sell dry bread or “instant” bread mixes?

Yes. Dry bread mixes are an acceptable product to produce and sell under the Cottage Food guidance document, as long as you meet all requirements of the law.

Does my chocolate fountain business qualify as a Cottage Food business? I deliver and set up the fountain, and provide chocolate dipping sauce and items to dip (cut up fruit, pretzels, etc.) that I have prepared in my home kitchen.

The type of business you have described is a catering service or food service business and is not eligible to operate under the Cottage Food guidance document. Cottage Food products must be prepackaged and properly labeled prior to sale.

Do I have to put a label on my Cottage Foods?

Yes, you are required to label your Cottage Foods. The basic information that must be on the label is as follows:

- Name and address of the Cottage Food operation.
- Name of the Cottage Food product (All capital letters or upper/lower case are both acceptable).
- The ingredients of the Cottage Food product, in descending order of predominance by weight. If you use a prepared item in your recipe, you must list the sub ingredients as well. For example: soy sauce is not acceptable, soy sauce (wheat, soybeans, salt) would be acceptable. Please see the following label for further examples.
- The net weight or net volume of the Cottage Food product (must also include the metric equivalent; conversion charts are available online).
- Allergen labeling as specified in federal labeling requirements.
- The following statement: "Made in a cottage food operation that is not subject to routine government food safety inspection" (all capital letters or upper/lower case are both acceptable).

Hand-printed labels are acceptable if they are clearly legible, written with durable, permanent ink, and printed large enough to equal the font size requirements listed above.

What does allergen labeling, as specified in federal labeling requirements, mean?

It means you must identify if any of your ingredients are made from one of the following food groups: milk, eggs, wheat, peanuts, soybeans, fish (including shellfish, crab, lobster or shrimp) and tree nuts (such as almonds, pecans or walnuts). So, if you have an ingredient made with a wheat-based product, you have two options:

1. Include the allergen in the ingredient list. For example, a white bread with the following ingredient listing: whole wheat flour, water, salt and yeast. In this example, the statement “whole wheat flour,” meets the requirements of federal law.
2. Include an allergen statement (“Contains:”) after the ingredient list. For example a white bread, with the following ingredients: whole wheat flour, water, sodium caseinate, salt and yeast. Contains wheat and milk.

The "Contains" statement must reflect all the allergens found in the product. In this example, the sodium caseinate comes from milk.

Are there any special requirements for tree nuts labeling for allergens?

Yes. If your Cottage Food has tree nuts as an ingredient, you must identify which tree nut you are using.

For example, if you made Nut Bread, an acceptable ingredient list would be:

Ingredients: wheat flour, water, almonds, salt, yeast.

The following would not be acceptable:

Ingredients: flour, water, nuts, salt, yeast.

I am concerned that some of my product ingredients that are not allergens are "trade secrets" and listing all my ingredients would lead to unfair competition. Do I have to list all of my ingredients or can I protect my trade secrets?

According to federal regulations (*Food and Drug Administration (FDA), 21CFR 101.100g(1)(2)*), exceptions to labeling can be made. In particular, if the Commissioner of Food and Drugs finds that alleged secret ingredients are harmless, an exemption may be granted. You should contact the [FDA](#) to discuss and propose an exemption from labeling.

Do I have to include my home address on my product labeling or is a post office box sufficient?

You must use the physical address of your home kitchen on your product label, not a post office box. The purpose of including an address on product labels is to be able to locate the business in case of a recall or traceback associated with a foodborne illness complaint or outbreak. The Cottage Food guidance document specifies that the name and address of the business of the Cottage Food Operation must be included on the label.

Am I required to send my products to a laboratory to obtain an official ingredient list, or is it something I can put together on my own?

You are not required to have your product analyzed by a laboratory to obtain an official ingredient list. You must, however, list all ingredients, in descending order of predominance by weight. If you use a prepared item in your recipe, you must list sub-ingredients as well. For example, if you use soy sauce as an ingredient, listing soy sauce is not acceptable; soy sauce (wheat, soybeans, salt) is acceptable. Allergen labeling, as specified in federal labeling requirements, must also be included.

If I make and sell wedding cakes, how can I meet the labeling requirements, when I can't stick a label on the cake?

For wedding cakes, birthday cakes and other specialty cakes that are not easily packaged, you must include all labeling requirements on the invoice and deliver the invoice with the cake. Smaller cakes must be boxed, and the label must be included on the box.

Why can't I sell my Cottage Foods to my favorite restaurant or grocery store?

Because the kitchen is not routinely inspected, the safe food handling practices are not evaluated by any food safety official. Since the safe food handling practices are not being evaluated, the food is not considered an approved source for use in a restaurant or grocery store. Also, it is not possible for the final consumer to discuss your food safety practices with you, since you are not selling or serving the product to the consumer.

Can I make and sell products from my motor home kitchen, or cottage or summer home?

The Cottage Food guidance document applies only to non-potentially hazardous foods made in the kitchen of your primary residence. Second homes, vacation homes or motor homes do not qualify if they are not your primary residence.

Can I make products in a rented kitchen and sell them?

No. The Cottage Food guidance document applies only to non-potentially hazardous foods made in the kitchen of your primary residence. Even if the rented kitchen is a licensed facility, you would need a food establishment license to sell your products.

Can I make Cottage Food products in an outbuilding on my property, like a shed or a barn?

No. The guidance document requires the Cottage Food products be made in your kitchen and stored in your single family domestic residence.

Where can I store ingredients and finished products for my Cottage Food business?

Ingredients and finished Cottage Food products may be stored in your single family domestic residence where the Cottage Food products are made. This includes your kitchen, a spare room or a basement that is free of dampness/water, pests or other insanitary conditions. You may not use a garage, shed, barn or other outbuilding as a storage facility for your Cottage Food business.

Can nonprofit organizations produce and sell Cottage Foods?

No. Nonprofits do not have a single family domestic residence and, therefore, do not qualify as a Cottage Food business.

Can I sell my Cottage Foods over the Internet?

No. While you can advertise your product on the Internet, you cannot take orders over the Internet and then ship directly to consumers. Sales and product delivery must be directly from the producer to the consumer, in a person-to-person transaction, and not delivered by mail.

Can I sell my Cottage Foods to a wholesaler, broker or distributor?

No. Under the Cottage Food guidance document, it is not legal for a producer to sell to a wholesaler, broker or distributor who would then resell the product.

Can I advertise my Cottage Food products on my website?

Yes. You can use your website to advertise your products or market your business, but cannot take orders or sell products via your website.

Can I advertise my Cottage Food business in the newspaper or at trade shows?

Yes. Advertising is allowed; however, the actual sale must be made person-to-person between the producer and the consumer.

Is it possible to place my Cottage Food products in a store or restaurant on consignment?

No. Cottage Food products cannot be sold on consignment. The sale must be person-to-person, from the producer to the actual consumer.

Can I serve free samples of my Cottage Food Products?

Yes. As long as your product meets the requirements of the Cottage Food guidance document and is a non-potentially hazardous food, sampling is allowed. Samples must be pre-packaged in your home kitchen (e.g., if you sample bread, you can't cut it at the market, but can cut it in your home kitchen and individually wrap or package the bread samples into sample cups with lids). Although you do not need an individual label for each sample, you must have properly labeled packages of your product on display with the samples so your customer can review the ingredient list. Your product cannot be cooked or prepared in a way that makes it a potentially hazardous food/temperature control for safety food (e.g., you can't add a dried dip mix to sour cream or serve anything that can't be kept safely at room temperature - these examples would require a food license).

**REQUIREMENTS AND RECOMMENDATIONS FOR APPLE CIDER PROCESSING
OPERATIONS
Revised July 2012**

INTRODUCTION

Untreated or raw apple cider has been linked to numerous foodborne illness outbreaks in the United States. It is a scientifically proven fact that pasteurization, ultraviolet light treatment, or an equivalent process, will eliminate foodborne pathogens from apple cider and thus ensure the safety of the product. Many producers of apple cider incorporate pasteurization, or other pathogen elimination procedures into their processes; consequently, much of the apple cider available to consumers is considered pasteurized, and causes little concern with respect to the presence of foodborne pathogens.

There is a segment of the apple cider industry that believes that pasteurization contributes undesirable characteristics to the product, and that consumers should have the right to choose between raw and pasteurized products. As a result, these guidelines have been developed to assist those producers in producing a product where the risk of contamination by foodborne pathogens has been significantly reduced.

The Food Committee of the Association of Food and Drug Officials under the guidance of Doug Saunders, Virginia Department of Agriculture and Consumer Services, developed these guidelines in 1999. Substantial input into the development of these guidelines was provided by both industry and government officials. The original basis for these guidelines was obtained from documents developed by the New York Department of Agriculture and Markets and the Michigan Department of Agriculture. The guidelines were revised by the Food Committee in 2011 to include new information obtained from documents developed by the Juice HACCP Alliance, Michigan Department of Agriculture, and the U.S. Food and Drug Administration.

AN AFDO MODEL CODE

May 26, 1999

Because fresh or untreated apple cider has been linked to numerous foodborne illness outbreaks, the Association of Food and Drug Officials believes that pasteurization, ultraviolet light treatment, or an equivalent process, is the only scientifically valid way to ensure the safety of apple cider. Since it may be unreasonable to expect that all apple cider processors will choose to pasteurize their products, the following requirements and recommendations for apple cider processing operations have been developed to significantly reduce the possibility that apple cider will be involved in future foodborne illness outbreaks.

DEFINITIONS

Dropped Apples: Apples that have contacted the ground in any manner in the orchard, storage cooler, pressing room or any other area. Where prudent precautions have not been taken to maintain separation of tree-picked and dropped apples, all apples shall be considered to be dropped apples.

Hazard Analysis Critical Control Point (HACCP): A prevention-based food safety system that identifies and monitors specific food safety hazards that can adversely affect the safety of food products.

Must: Term used to state mandatory requirements.

Pasteurized: Apple cider which has been produced by a method that includes a processing step (typically a heat process) which has been shown to achieve a 5 log (99.999%) reduction of pathogens.

Patulin: A mycotoxin produced by certain species of molds that grow on a variety of foods including apples and pears.

Sanitation Standard Operating Procedures (SSOPs): Written procedures necessary to ensure sanitary conditions in a food processing establishment.

Shall: Term used to state mandatory requirements.

Should: Term used to state recommended or advisory procedures; or identify recommended equipment.

Tree-Picked Apples: Apples which have been picked directly from the tree and segregated under sanitary conditions from dropped apples.

Ultraviolet light (UV) Treated: Apple cider which has been produced by a method that includes exposure of apple cider to ultraviolet light at a level shown to achieve a 5 log reduction of pathogens.

Untreated Apple Cider: Apple cider which has been produced by methods that do not include a processing step to achieve a 5 log reduction of pathogens.

GENERAL

The use of a Hazard Analysis Critical Control Point (HACCP) program is strongly recommended.

FACILITY REQUIREMENTS

Cider processing and other food-processing operations must be located in a separate, enclosed room or building. The food processing room must have impervious walls and ceilings, and the floors must be continuous concrete or other equally impervious and cleanable material with adequate floor drains.

Walls and ceilings should be light colored for easier cleaning and to provide better lighting on all work surfaces.

The processing facility must be adequately screened to eliminate insect and rodent entry. Cold storage door plastic curtains are effective where entrance is by forklift. During the cider-processing season, overhead garage door openings can be framed in with temporary screened panels and a walk-in door provided. Temporary screens should be constructed in a manner, which allows the garage doors to be closed whenever desired.

Completely enclosed toilet facilities must be provided and should be conveniently located near the work area. Conveniently located hand wash facilities must be provided, and must have hot and cold running water and soap for hand washing. In addition, there must be a suitable hand drying device or disposable towels and covered trash containers. A sign must be placed in the bathroom reminding employees to wash their hands.

Adequate lighting must be provided. All lights over exposed food areas must be shielded to prevent pieces of glass from getting into food in the event of bulb or tube breakage.

Grounds and buildings surrounding the cider operation must be free of conditions, which may result in contamination of the product. This includes improperly stored equipment or spray materials, litter, waste, uncut weeds and grass and other rodent or pest harborage.

Disposal of all wash and wastewater shall be through an approved sanitary sewage disposal system that is sized, constructed, maintained and operated according to law.

Equipment, utensils, chemicals and supplies not used in food processing must be stored in an area clearly separated from those used in food processing.

Cleaning chemicals, such as Clean-in-Place (CIP) chemicals, must be stored separately from pesticides or other non-processing chemicals.

Hot and cold potable, running water must be available in all processing areas. Sufficient volume and water pressure must be available to dislodge particles of fruit and film from all surfaces. A high-pressure washer is highly recommended.

If well water is used, it must be tested by a certified lab at least annually to meet potability standards. The test should be done within two months prior to the commencement of seasonal apple cider operations.

The use of insecticides and rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging material with illegal residues. If used within the processing area, precautions must be taken to protect all raw ingredients and packaging materials. After spraying and before commencement of any food processing operation, all food contact surfaces must be thoroughly cleaned and sanitized.

EQUIPMENT

All food contact surfaces must be constructed of food-grade materials that are safe, durable, corrosion-resistant, non-absorbent and can be easily cleaned and sanitized. Copper, copper alloys and galvanized metals must not be used in contact with apple cider.

All food contact equipment and supplies (examples: racks, cloths) must be stored off the floor in a well-ventilated location, which minimizes the potential for contamination.

All tubing carrying cider must be approved for food use and all plastic tubing should be transparent for ease of inspection and cleaning. Tubing must be protected from abrasion or breakage and easily replaced. If the tubing passes through spaces that are not readily accessible, the tubing should be one piece and easily cleaned. Tubing should be as continuous as possible with couplings kept to a minimum. Periodic disassembling, cleaning and sanitizing of tubing, clamps, couplings and connections must be performed. Tubing must be positioned so that no pockets of liquid remain when the tubing is rinsed (self-draining). Tubing must be cleaned and sanitized at least after each day's run and prior to use following extended interruption.

EMPLOYEES

Competent supervisory personnel must be assigned the responsibility of supervising the overall sanitation of the facility.

To prevent contamination of food products, all persons working in the processing and filling areas must wear clean outer garments, maintain a high degree of personal cleanliness and conform to hygienic practices while on duty. Hands must be washed thoroughly before starting work, after each absence from the working area, between operations and any other time when they have become soiled. All insecure jewelry shall be removed. Hair restraints (hairnets, headbands, caps, etc.) must be worn. If gloves are used, they must be designed for food handling operations. Whenever personnel change from non-food contact or cleaning operation to food contact operation, the individual must replace gloves or wash hands thoroughly before resuming food contact operations.

Tobacco in any form must not be used in rooms where food or food ingredients are processed, handled or stored.

A person who has diarrhea or is a carrier of a communicable disease that can be transmitted by food is prohibited from working with cider apples or in the processing area.

HARVESTING

Steps can be taken in the orchard to minimize microbial contamination of apples. Where possible, orchards should be fenced in order to restrict or eliminate animal grazing in the orchard. If orchards are frequented by large flocks of starlings or other roosting birds, soiled fruit should not be used in unpasteurized cider. Care should be taken during collection to prevent the contact of damaged apples with wholesome fruit.

Eliminate to the extent possible animal droppings and manure in the orchard. Unpasteurized apple cider must not be made from apples of orchards fertilized with human or animal wastes.

Dropped apples must not be used for the production of unpasteurized cider.

Good hygienic practices should be used by those collecting apples and toilet and hand washing facilities should be readily accessible to field workers.

Know the quality of the apples from which you will be making your cider. More contaminated apples coming into your process will require more stringent inspection and cleaning to make safe cider. The use of written contract specifications is highly recommended for cider producers who purchase cider apples.

Clean containers must be used to harvest and transport apples. Containers should be properly maintained and inspected continually throughout the season.

RECEIVING

If cider apples are purchased, accurate records should be kept of incoming lots, which identify the date of purchase and source of apples used to produce each lot of cider. Accurate records can limit product recalls and producer liability in the event of an outbreak.

Processing apples should be kept in cold storage, as close to 32°F as possible, or in an enclosed area, free of flies, other insects, rodents and other pests. Lower temperatures extend product shelf life considerably.

Animals (cats, birds, dogs, wild animals, etc.) are prohibited from processing and storage areas of the building.

Apple containers should be inspected upon receipt and before apples are used to assure the containers are free of visible filth which may contaminate the apples.

INSPECTION

All apples must be inspected before or during washing and brushing. Only intact, sound apples shall be used. Wormy, decayed or rotten fruit must be discarded before entering the washing step. Only intact, sound tree-picked fruit shall be used in the production of unpasteurized apple cider. Damaged fruit (i.e., hail damage, etc.) may be used as long as such damage does not negatively impact the microbiological quality of the fruit. Otherwise, damaged fruit must be discarded before entering the washing step.

Fruit should be dry-dumped for inspection to prevent heavily soiled apples from spreading contamination via wash water.

If a flume is used, flume water must be of potable quality. Additionally, potable water or its equivalent must be used as a final rinse prior to pressing.

If field crates are floated in flume water, pressure washing the bottoms of crates before submerging them in flume water is recommended.

WASHING AND BRUSHING

Apples must be thoroughly washed and cleaned (free of visible filth and debris) before brushing. This can be accomplished as part of the grading operation if there is no storage or holding time between grading and pressing.

Use of a food grade detergent and sanitizer in accordance with the manufacturer's label specifications to further reduce biological contamination is recommended.

CRUSHING AND PRESSING

Crushing and pressing equipment must be cleaned and sanitized prior to start-up and at the end of each day of operation at a minimum.

Equipment must be dismantled or disassembled at least daily to insure adequate cleaning and sanitizing. Do not rinse equipment after sanitizing. All equipment must be air-dried.

Press cloths must be specifically designed for cider production, made of durable materials and be replaced frequently. During processing, the cloths must be handled in a sanitary manner, which includes hanging the cloths on a line or placing them in a clean container off the floor between runs. At the end of each day's operation, all press cloths must be washed, rinsed, dipped in sanitizing solution and dried. The cloths may be dried by spreading them on a clean line in a well-ventilated and screened area away from flies and vermin. If a washing machine is used, it must be dedicated solely for the cloths and not for personal and work clothing.

Press racks must be made of food-grade plastic or hardwood which has been maintained free of excessive cracks or crevices. Poorly maintained equipment can be impossible to clean and sanitize adequately.

Keep press racks off the floor at all times. At the end of each day, all used press racks must be washed, sanitized and allowed to dry.

Pressed pomace must be properly disposed of immediately. Pomace residue must not be left overnight in the processing area. Pomace residue removal helps control insects and rodents on the property.

PATULIN CONTROL MEASURES

The FDA action level for patulin is 50 parts per billion. Patulin is reported to be destroyed by fermentation; however, thermal processing appears to cause only moderate reduction in patulin levels.

Control of patulin levels can be most practically accomplished by removing spoiled or visibly damaged apples prior to crushing and pressing. This can be achieved by culling or trimming apples after storage; or if receiving apples, a supplier guarantee specifying that dropped apples were excluded from the shipment. More information on patulin control is available in FDA's 2004 Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition.

ADDITIVES

If additives (e.g., sodium benzoate and potassium sorbate) are used, care must be taken to assure they are used in accordance with good manufacturing practices and as specified in Title 21 of the Code of Federal Regulations. [Studies have shown a combination of both sodium benzoate and potassium sorbate at 0.1% each, to be most effective in controlling *E .coli O157:H7*.]

AFTER PRESSING

Thermal pasteurization or UV treatment is recommended, as is the use of microbiological testing procedures, on production batches to identify sanitation failures or product contamination. In order to guarantee that the pasteurization equipment you plan to use incorporates those design features necessary to insure your cider has been properly pasteurized, it is recommended that you submit a schematic of the pasteurizer to the regulatory authority for review (see addendum titled "Apple Cider - Thermal Pasteurization Equipment Recommendations"). While end product testing may not be a complete assurance that the cider is free of pathogens, indicator organisms such as coliforms or generic *E coli* may help determine if adequate and consistent sanitation is being practiced. Testing may also play a role in HACCP plan verification and establishes a quality history.

Cider must be bottled in new containers and caps which have been properly stored to be free of dust, debris and insects. Containers must be stored in their original closed plastic bags and inverted with the open tops down to avoid environmental contamination. Inspect containers carefully before filling, and/or sanitize them thoroughly. Refilling used consumer containers risks contamination of filling equipment and cider and can take place only in a manner approved by the regulatory authority.

ULTRAVIOLET (UV) TREATMENT

The use of ultraviolet irradiation is recognized as an acceptable alternative to thermal pasteurization as a means to achieve the 5-log reduction performance standard required for apple cider. The process works by exposing juice to ultraviolet light at a level which breaks down the DNA of microorganisms. Currently ultraviolet light is mostly used by small juice processors due primarily to flow rate.

The level of UV necessary to kill microorganisms can vary depending on the composition and color of the juice. Therefore, the use of UV treatment requires proper validation and documentation of the 5-log reduction process. Validation of the process must be conducted by a recognized process authority. Adequate controls must be in place with supporting records to verify the process has been properly implemented. Typical controls for currently approved UV systems may include:

- A validation document signed and dated by the recognized process authority.
- Auto-calibration performed at start-up for lamp function, UV sensors, and pump flow rate.
- Tamper evident seals on quartz sensors.
- Printed fault occurrences (supported by corrective action records).

LABELING

Containers must be properly labeled with the following information:

- Product identity -- Apple Cider
- Ingredients (if additives are used)
- Name, address, city, state and zip code of manufacturer, packer or distributor
- Net quantity

Nutritional labeling, as identified in Title 21, Part 101 of the Code of Federal Regulations (21 CFR 101), may also be required.

The statement, "**IMPORTANT: Must be Kept Refrigerated,**" should appear on the label as well as meaningful coding which identifies the packing period.

Where used, pasteurization or UV treatment processes are not required to appear on the product label; however, this information may be useful to consumers. It is not permissible to use the term "pasteurized" on labels in place of "UV treated".

Federal regulations require warning statements on labels of packaged juice products that have not been processed in a manner that will produce a reduction in pathogenic microorganisms to an acceptable level. The required warning statement, identified in 21 CFR 101.17 (g), reads as follows:

WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

Those operators who produce apple cider that has not been processed in a manner that will produce a reduction in pathogenic microorganism to an acceptable level, but do not fall within the requirements of 21 CFR 101.17 (g), are encouraged to implement such a labeling program to inform at-risk consumers of the hazards that may be associated with such products.

OFF-SEASON

During the off-season, press racks and cloths should be stored so that birds, animals, insects, etc., are unable to come in contact with them. Thoroughly clean, sanitize, dry, and wrap racks and cloths before storage.

While none of the foregoing requirements and recommendations can guarantee pathogen-free cider, their implementation will serve to greatly reduce the possibility that your cider will be involved in a foodborne disease outbreak. The use of Standard Sanitation Operating Procedures (SSOPs) and a Hazard Analysis Critical Control Points (HACCP) plan is also strongly recommended.

These guidelines are based on currently available scientific information and will be revised and updated as researchers learn more about pathogens of concern in cider and their control.

ADDENDUM TO REQUIREMENTS AND RECOMMENDATIONS FOR APPLE CIDER PROCESSING

Apple Cider Thermal Pasteurization Equipment Recommendations May 26, 1999

Currently available scientific information suggests that adequate pasteurization for apple cider produced from most varieties of apples is achieved at a temperature of 160°F for 6 seconds. An exception to this is cider produced from "*Red Delicious*" apples which requires a temperature of 160°F for 11 seconds or 170°F for 2 seconds.

Consumers and apple cider processors alike should have confidence that cider which is labeled pasteurized has in fact undergone an adequate pasteurization process. We believe that compliance with the following apple cider pasteurization equipment recommendations can help provide reasonable assurance that your cider has been properly pasteurized.

RECORDER CONTROLLER

- A. **Purpose:** To automatically record pasteurization temperatures and times and automatically control the position of the flow diversion device.
- B. **Location:** The sensor should be located within 18 inches of, and upstream from, the flow diversion device.
- C. **Design and Operation:** The recorder controller or Safety Thermal Limit Recorder (STLR) is an electronic instrument actuated by either a Bourdon coil attached to an ether derivative (water and glycerin) filled capillary which responds to temperature changes or may be one of the newer type electronic programmable recorder controllers which utilize electronic remote temperature sensing devices and computer logic.

INDICATING THERMOMETER

- A. **Purpose:** To indicate the accurate temperature of the product.
- B. **Location:** At the end of the holding tube and as close as practicable to the recording thermometer sensor.
- C. **Specifications:**
 - 1. Type:
 - a. Mercury In Glass (MIG) - Mercury actuated, direct reading, corrosion resistant case.
 - 1) Scale: Span not less than 25°F including pasteurization temperature plus or minus 5°F, graduated in 1.0°F divisions.
 - 2) Accuracy: Tested against known standard upon installation and then at least once a year thereafter.
 - 3) Thermometric response: 4 seconds to travel 63% (12° which includes the pasteurization range) of a 19° span.

- b. Digital Reference Thermometer (DRT) - On November 27, 1991, the FDA, through M-b-314, allowed the use of the digital reference thermometer (DRT) as a replacement for the mercury actuated (MIG) indicating thermometer for use in pasteurization systems.
 - 1) Scale: Temperature indicated to at least 0.1°F.
 - 2) Accuracy: Tested against known standard upon installation and then at least once a year thereafter.
 - 3) Thermometric response: 4 seconds to travel 63% (12° which includes the pasteurization range) of a 19° span.

HOLDING TUBE

- A. **Purpose:** Section of piping of sufficient length to provide a minimum holding time at a predetermined temperature for heated product in a continuous flow pasteurizer.
- B. **Design and Operation:**
 - 1. Permanent supports to assure alignment and proper slope to preclude air entrapment and assure uniform product flow. The minimum upward slope is 0.25 inch per running foot, or 2.1 centimeters per meter.
 - 2. Fabricated to eliminate short circuiting (no alterable sections).
 - 3. Starts at the salt injection port and ends at the flow diversion device.
 - 4. Designed to assure temperature variation not to exceed 1°F.
 - 5. Heat should not be applied to the holding tube at any point.

TIMING (METERING) PUMP

- A. **Location:** In basic High Temperature Short Time (HTST) systems, the conventional timing pump will be the only flow promoting device in the system. Timing pumps, when used in systems with product-to-product regenerators, should always be placed downstream from the raw regenerator. This is to assure that, during operation, raw product pressures in the product-to-product regenerator are relatively less than pressures on the pasteurized side of the plates. Timing pumps may be speed adjustable but are always set at the fastest minimum legal pasteurization time(s) and sealed to prevent unauthorized changes. Some timing pumps are electronically controlled, and this controller should also be sealed to prevent unauthorized changes. Timing pumps may operate at any time except when the dual stem flow diversion device mode switch is in the "**Inspect**" position or unless during the diverted flow, the flow diversion device is properly assembled and the microswitch is in the proper position.

B. Types:

1. Positive displacement type: Positive pumps may be of several types, two of which are in common usage in the continuous flow pasteurizer.
 - a. Gear driven type pump (where two rotors or impellers revolve within an oval case). Close tolerances between the gears and the outer case make the space or pockets between the teeth or lobes carry the fluid around the periphery of the pump body. The size of these pockets and the speed at which they revolve determine the volume that will be pumped. It is important to remember that the efficiency of these impeller-type pumps may be greatly influenced by the temperature and type of liquid they are pumping. This becomes important when performing the holding time test for systems with these types of pumps.
 - b. Belt/pulley driven piston type pump such as the homogenizer. Homogenizers are very efficient positive displacement pumps and are frequently used as the timing pump in continuous pasteurizers.
2. Magnetic flow meter based system which uses a centrifugal pump in conjunction with product flow controlling methods.
3. Centrifugal pumps.

C. Controls:

1. The timing pump should be considered operating at maximum speed and capacity to assure that the minimum holding time requirements are satisfied.
2. The pump should also be interwired with the flow diversion device and recorder controller. This is to prevent the flow of raw product into the pasteurized side of the system.
3. Generally, there is only one primary timing device in the system. When two positive displacement pumps are used as timing pumps, both should be timed separately and together to assure minimum holding times are achieved.

FLOW DIVERSION DEVICE (FDD)

High Temperature Short Time (HTST) continuous flow pasteurization equipment should be equipped with either a single or dual stem FDD.

A. Single Stem:

1. Purpose: To safely and accurately control and separate raw and pasteurized product flow.

The single stem flow diversion device is a specially designed three-way valve that, in conjunction with a recorder controller, is capable of automatically controlling the direction of product flow in a pasteurizing system. It should be manually cleaned.

2. Operation:
 - a. The single stem flow diversion device is air activated for the open position (forward flow) and spring activated for the closed (divert or fail-safe) position. To activate (open) the valve, compressed air is admitted

above the diaphragm. This compresses the spring and moves the valve to seal off the divert line and opens the forward flow port. Compressed air to the top of the diaphragm is controlled through an air-activated solenoid valve.

This solenoid is activated by a signal from the recorder controller microswitch when the preset cut-in temperature is reached. Loss of air pressure or electrical signal from the recorder controller causes the spring to automatically return the valve to the closed or fail-safe divert position.

- b. When the flow diversion device is properly assembled and in the fully diverted position, the microswitch roller will be positioned in the valve diaphragm push plate groove. In this position, the microswitch provides power to the timing pump and the red light on the recorder controller.
 - c. When the flow diversion device is in the forward flow position, the roller rides above the groove and the microswitch energizes the green light and the frequency pen arm on the recorder controller. During legal forward flow, the timing pump is energized by the recorder controller switch.
 - d. If during diverted flow the diversion device is not properly assembled or seated, the microswitch roller will be mispositioned out of the groove and the timing pump will not run. This prohibits any raw product from entering the forward flow port of the valve during divert.
3. Basic Requirements:
- a. Systems should be provided to insure proper operation of the FDD to operate only when properly assembled and then only when in the fully forward or fully diverted position.
 - b. It should be impossible to tighten the stem packing nut so as to prevent the valve from assuming the fully diverted position within the prescribed time (1 sec.).
 - c. Leak escape ports should be unobstructed and on the forward flow side of the flow diversion device seat. The forward flow seat should close tight enough so that any leakage past the seat will not exceed the capacity of the leak escape device. The poppet valves, as they are known, are held in place by springs and "O rings." When the valve is in diverted flow, the leak detectors allow product that leaks past the sealing rings (gaskets) of the valve plunger to escape to the atmosphere. In forward flow the springs hold these poppets against their seat preventing leakage. Product pressures in excess of 20 psi may prevent their proper seating and result in leakage.

- d. The length of the connecting rod should not be adjustable. Power failure or loss of air pressure should automatically move the valve to the fail-safe (*diverted*) position. The flow diversion device should be located downstream from the holding tube. The divert line should be self-draining and should be free of restrictions or valves unless readily identifiable and are so designed that stoppage of the divert line cannot occur.

B. Dual Stem:

1. Purpose:
 - a. To safely and accurately control and separate raw and pasteurized product flow.
 - b. A dual stem flow diversion device is basically two, three-way valves in tandem which automatically control the direction of product flow. This type of valve or device was designed to be cleaned in-place.
2. Operation:
 - a. Each manufactured brand of valve is slightly different in design; however, all have two bodies with an interconnecting yoke, pneumatic actuators and spring-loaded valve plungers.
 - b. All are designed to move to, or remain at, the fail-safe divert position in the event of loss of power or air pressure.
 - c. Each valve is actuated by a quick exhaust type solenoid valve that controls the air to each valve.
 - d. Microswitches (or proximity switches on some models) are located near the top of each actuator stem in the valve bonnet, and operate and function identical to those in the single stem flow diversion device. (Control power signal to the timing pump, frequency pen and panel indicator lights).
3. Basic Requirements:
 - a. Systems should be designed to insure proper operation of the flow diversion device only when properly assembled and only when in the fully forward or fully diverted position.
 - b. It must be impossible to tighten the stem packing so as to prevent the valve from assuming the fully diverted position within the prescribed time (< 1 sec.).
 - c. Leak escape ports must be unobstructed and on the forward flow side of the flow diversion device seat. The forward flow seat should close tight enough so that any leakage past the seat will not exceed the capacity of the leak escape device. This requirement design should eliminate any back pressure from being applied to the divert and leak detect ports of the flow diversion device.

- d. The length of the connecting rod should not be adjustable.
- e. Power failure or loss of air pressure should automatically move the valve to the fail-safe (diverted) position.
- f. The flow diversion device should be located downstream from the holding tube.
- g. The divert line should be self-draining and should be free of restrictions or valves unless readily identifiable and are so designed that stoppage of the divert line cannot occur.
- h. The leak detect line should be designed to discharge all leakage to the outside or to the constant level tank. This leak detect line must be separate from the divert line and should not have any restrictions.

A sight glass must be installed in the leak detect line if connected to the constant level tank. This sight glass must be of the full see-through (clear material providing vision on both sides of the cross fitting) design and be installed in the vertical line.

The only exception to this requirement is the provision for a transparent tube assembly which may be installed horizontally.

- i. All dual stem valves which have both bodies mounted vertically must have sealed time delays. There is a newer model of the G&H FDD that is exempt from this requirement because of the connecting "yoke" configuration. These time delays are as follows:
 - 1) At least one second between actuation of the divert valve and the leak detect valve when moving from the diverted flow to the forward flow position. The purpose of this is to flush the connecting line of any possible raw product remaining in this connecting "yoke." On systems having identifiable restrictors in the divert line, the maximum time delay (divert valve to leak detect valve "flush time") should never exceed five seconds which prevents the possibility of underprocessed product (< 15 seconds) from entering into the pasteurized side of the system.
 - 2) When the switch is moved from "**PRODUCT**" or "**PROCESS**" to the "**INSPECT**" position, the valve should immediately assume the "**DIVERT**" position and all flow promoting devices should be immediately de-energized. After all flow promoting devices have completely stopped (or have been effectively valved out of the system) the flow diversion device may move to the "**FORWARD FLOW**" position for inspection or servicing.

- 3) A maximum of one second time delay is allowed during transition movement times of the flow diversion device provided that a one second maximum "off" time delay is allowable to maintain the flow promoting device in the "on" position through the travel time of the valve(s) (NCIMS-93). This removes the requirement for de-energizing the flow promoters (i.e., timing pumps) during times required for the flow diversion device to move to the forward or divert flow position.

REGENERATOR PRESSURE RELATIONSHIPS

- A. **Purpose:** Pasteurized and raw products are separated by only thin stainless steel plates and a series of gaskets in the regenerator section. That is the reason that the pasteurized product **SHOULD ALWAYS** be under greater pressure than the raw product in the system. In the event of leakage due to either gasket or metal failure, the pasteurized product will be forced into the raw side of the regenerator and not vice versa.
- B. **Operation:** This pressure relationship should always be maintained during all phases of operations. This includes initial start-up, during processing (including diverted flow), and during any periods of sudden loss of power or shutdown.
- C. **Basic Requirements:**
 1. The overflow level of the balance tank should be lower than the product level within the regenerator.
 2. The timing pump should be located between the outlet of the raw regenerator and the beginning of the holding tube.
 3. No pump, other than a properly designed, installed and operated booster pump, should be installed between the balance tank and the raw product inlet to the regenerator.
 4. Generally, the product should enter the raw side of the regenerator at the bottom, unless the system has a start-up regenerator bypass line, properly valved to allow unobstructed drainage of raw product back to the balance tank during loss of power or shutdown.
 5. Pasteurized product at the outlet from the pasteurized regenerator should rise to a vertical elevation of at least 12 inches above the highest raw product in the pasteurizer system and at that point or higher should be open to the atmosphere through a sanitary vacuum breaker.
 6. No flow promoting device which can affect the pressure relationships within the regenerator may be located between the pasteurized product outlet of the regenerator and the vacuum breaker.

7. During shutdown or loss of power, the vacuum breaker closes off the product line resulting from atmospheric pressure being applied on the breaker disc. This produces a capillary-type action holding the pasteurized product with the 12-inch rise of piping which produces a back pressure on the pasteurized side of the product-to-product regenerator to approximately 1 psi. The pasteurized product is simultaneously held in a static position by the forward flow valve seat of the flow diversion device, which prohibits any back drainage into the holding tube. During this time, the raw product is undergoing a pressure reduction which is facilitated through the small drilled holes in the raw product deflector plates located at or near the bottom of the plate. To facilitate this, the outlet to the raw product regenerator may be disconnected.

All frequency controllers, if used, should be set at 60 Hz during pasteurization cycle. Clean-in-Place (*CIP*) function is exempt from this requirement.

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- Courtney Rheinhart, Virginia Department of Agriculture & Consumer Services

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March 18 - 21, 2013

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