



Journal of the Association of Food and Drug Officials

Serving the regulatory community since January 1937

Contents of this Issue

	<u>Page</u>
From the Executive Director	1
2011-2012 AFDO Board of Directors	3
2011-2012 AFDO Board-Appointed Advisors	3
2011-2012 AFDO Committee Chairpersons.....	4
AFDO Regional Affiliates	5
2011 AFDO Award Recipients	6
2011 AFDO Resolutions	7
2011 AFDO Position Statements.....	15
About the Authors.....	19
President's Address	23
Glenn W. Kilpatrick Address	25
The Impact of the Food Safety Modernization Act on Federal-State Relations .	31
CFIA Keynote	35
Product Tracing in Food Systems: The Institute of Food Technologists' Recommendations to FDA	43
Elements of the IFPTI Training System	49
Don't Be Haunted By Your Words!	62
From the AFDO Archives (1938).....	68
Coordination of State Drug and Pharmacy Laws.....	68
Where Are We Headed -- And For What Are We Striving In Regulatory Control Activities	75
NASDA News Release: 2011 Raw Milk Survey.....	81
AFDO Publications	84
Guidelines for Exempt Slaughter and Processing Operations, Rev. June 2011..	84
Retail Meat and Poultry Processing Guidelines, Rev. June 2011	102

[This page intentionally left blank]

From the Executive Director

One thing is certain about AFDO – they never give up!

A number of years ago, the Association began discussing with FDA the idea of forming an “Alliance” for state food safety program managers. As you know, it was AFDO that first offered a vision for integrating the nation’s food safety system and we have, for some time, believed an Alliance of state programs could help advance the idea and make it a reality. It was great talk, but little action -- until recently when FDA began to implement a number of initiatives with associations, universities, and IFPTI that were designed to advance the concept of integration. It sure looks good for all of us who have wished to see integration emerge as a priority to FDA. Recent events clearly indicate that FDA fully intends to integrate with state and local agencies.

For our part, AFDO has been awarded funding from FDA to establish an “Alliance for Advancing a National Food safety System”.

The goal of the Alliance is to facilitate long-term improvements to the national food safety system by strengthening inter-agency collaboration; improving States’ regulatory and surveillance protection programs for manufactured foods; and providing assistance to state legislatures.

Some of the functions of the Alliance will be as follows:

1. Assist FDA in meeting provisions of the Food Safety Modernization Act (FSMA);
2. Support the efforts of federal, state, and local government agencies to integrate the national food safety system;
3. Implement pilot projects between states and FDA Districts for the purpose of demonstrating effective integration of resources and authorities;
4. Establish a network system to better access and share food safety information and data;
5. Assist FDA and the International Food Protection Training Institute (IFPTI) in the identification, development, and/or delivery of food safety and defense training programs;
6. Support the continued advancement of the Manufactured Food Regulatory Program Standards (MFRPS); and

7. Conduct a national meeting of state food safety manufactured food program managers and FDA officials, as needed, to address Alliance issues.

Alliance participants will consist of state food safety program managers who supervise the inspection of food manufacturing and distribution facilities -- except for dairy products and shellfish -- addressed through existing cooperative programs.

Through this Alliance, AFDO will enhance widespread influence by formalizing this community and bringing them together for annual face-to-face meetings to support the advancement of the Manufactured Food Regulatory Program Standards (MFRPS); to better access and share food safety information and data; to push efforts and conduct pilot projects to advance a national integrated food safety system; and assist FDA in meeting the provisions of the Food Safety Modernization Act (FSMA). Through this Alliance, AFDO will also continue to conduct surveys, such as the AFDO State Food Safety Resource Survey, and administer the Directory of State and Local Officials that is now available on AFDO and FDA websites.

We never gave up on integration, and we never gave up on this Alliance proposal. Thanks to everyone for hanging tough!

Joseph Corby
AFDO Executive Director

2011-2012 AFDO Board of Directors

<i>President*</i> ▼	Oscar Garrison
<i>President-Elect*</i> ▼	Claudia Coles
<i>Vice-President*</i> ▼	Terri Wenger
<i>Secretary/Treasurer*</i> ▼	Steve Moris
<i>Past-President</i>	Ron Klein
<i>Executive Director</i>	Joseph Corby
<i>Association Manager</i>	Denise Rooney
<i>Director-at-Large*</i> ▼	Stephen Stich
<i>Director-at-Large</i> ▼	Mark Reed
<i>FDA Advisor</i>	Joseph Reardon
<i>USDA Advisor</i>	Ralph Stafko
<i>DHS Advisor</i>	John Martin
<i>CDC Advisor</i>	Carol Selman
<i>Health Canada Advisor</i>	Robert Scales
<i>CFIA Advisor</i>	Bill Teeter
<i>AFDOSS Regional Affiliate Director</i> ▼	Pamela Miles
<i>CASA Regional Affiliate Director*</i> ▼	Alan Taylor
<i>MCAFDO Regional Affiliate Director</i> ▼	Stan Stromberg
<i>NCAFDO Regional Affiliate Director</i> ▼	David Read
<i>NEFDOA Regional Affiliate Director</i> ▼	Darby Greco
<i>WAFDO Regional Affiliate Director</i> ▼	Susan Parachini

* Member of Executive Committee

▼ Voting Board Member

2011-2012 AFDO Board-Appointed Advisors

Kevin Armbrust, Mississippi State Chemical Laboratory

Dennis Baker, U.S. Food & Drug Administration

Cynthia Culmo, Abbott Laboratories

Sarah Geisert, General Mills, Inc.

Kent Kitade, California Department of Food & Agriculture

Dan Sowards, Texas Department of State Health Services (retired)

Jerry Wojtala, International Food Protection Training Institute

2011-2012 AFDO Committee Chairpersons

Administration Committee

*Doug Saunders** (804) 786-8905
VA Dept. of Agriculture & Consumer Svcs.
doug.saunders@vdacs.virginia.gov

Alan Taylor (410) 767-8447
MD Dept. of Health & Mental Hygiene
alant@dnhm.state.md.us

Associate Membership Committee

*Sarah Geisert** (763) 764-2595
General Mills, Inc.
sarah.geisert@genmills.com

Cynthia Culmo (951) 914-3369
Abbott Vascular
cynthia.culmo@abbott.com

Drugs, Devices & Cosmetics Committee

*Thomas Brinck** (512) 834-6755
TX Dept. of State Health Services
tom.brinck@dshs.state.tx.us

Dennis Baker (214) 253-4904
FDA/U.S. Food & Drug Administration
dennis.baker@fda.hhs.gov

Food Committee

*Ellen Laymon** (503) 671-9711
FDA/U.S. Food & Drug Administration
ellen.laymon@fda.hhs.gov

Byron Beerbower (517) 241-0934
MI Dept. of Agriculture
beerbowerb@michigan.gov

James Melvin (919) 733-7366
NC Dept. of Agriculture & Consumer Svcs.
jim.melvin@ncagr.gov

Food Protection & Defense Committee

*David Read** (651) 201-6596
MN Dept. of Agriculture
david.read@state.mn.us

Mike Starkey (651) 201-6286
MN Dept. of Agriculture
Michael.starkey@state.mn.us

International & Government Relations Committee

*Malcolm Frazier** (404) 253-1171
FDA/U.S. Food & Drug Administration
malcolm.frazier@fda.hhs.gov

Robert Scales (204) 983-3004
Health Canada
Robert.Scales@hc-sc.gc.ca

Laboratory, Science & Technology Committee

*Yvonne Salfinger** (850) 617-7555
FL Dept. of Agriculture & Consumer Svcs.
yvonne.salfinger@freshfromflorida.com

Dan Rice (518) 457-4477
NY State Dept. of Agriculture & Markets
daniel.rice@agmkt.state.ny.us

Laws & Regulations Committee

*Terri Wenger** (608) 224-4714
WI Dept. of Agriculture
terri.wenger@wisconsin.gov

Seafood Committee

*Rita Johnson** (813) 929-1097
FL Dept. of Agriculture & Consumer Svcs.
rita.johnson@freshfromflorida.com

Gary Wolf (856) 783-1398
FDA/U.S. Food & Drug Administration
gary.wolf@fda.hhs.gov

*Chair is responsible for submission of reports

AFDO Regional Affiliates

Association of Food and Drug Officials of the Southern States

AFDOSS President.....Charlene Bruce
(601) 201-0164
charlenewbruce@aol.com

Central Atlantic States Association

CASA President.....Rachel Weinblum
Allegheny County Health Department
(412) 578-7923
rweinblum@achd.net

Mid-Continental Association of Food and Drug Officials

MCAFDO PresidentSteven Moris
Kansas Department of Agriculture
(785) 296-5600
Steve.moris@kda.ks.gov

North Central Association of Food and Drug Officials

NCAFDO PresidentClark Hepper
South Dakota Department of Public Health
(605) 773-4945
Clark.hepper@state.sd.us

North East Food and Drug Officials Association

NEFDOA PresidentTracey Weeks
Connecticut Department of Public Health
(860) 509-7297
tracey.weeks@po.state.ct.us

Western Association of Food and Drug Officials

WAFDO PresidentDawn Smith
Oregon Department of Agriculture
(503) 986-4726
dsmith@oda.state.or.us

2011 AFDO Award Recipients

The Inaugural **Elliot O. Grosvenor Food Safety Award** was presented to the **North Carolina Department of Agriculture and Consumer Services**. Dan Ragan 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, **Cameron Smoak**, was honored for his outstanding service and devotion to the administration of food, drug and consumer protection laws of our country. Mr. Smoak served the Georgia Department of Agriculture for more than 30 years.

The **Associate Member Award** was presented to **Michael Roberson**, Director of Corporate Quality Assurance for Publix Super Markets Inc. of Lakeland, Florida. 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 2011 **Achievement Award** was presented to **Terry Taynton**, Sanitation & Safety Specialist, Bureau of Food & Meat Inspection Division of Food Safety, with the Florida Department of Agriculture. 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:

Sarah Chandler, Eastern Kentucky University

Chelsey Keller, Cornell University

Audra Wallis, University of Tennessee

2011 AFDO Resolutions

RESOLUTION NUMBER 1

Submitted by: Charlene Bruce, President-AFDOSS, and Rita Johnson, Co-Chair for AFDO Seafood Committee, as submitted by the Seafood Committee member, Dr. Steve Ottwell, Food Science & Human Nutrition Department, University of Florida

Date: May 2, 2011

Concerning: Public health messages and advisories regarding potential risk due to mercury content in seafood consumption

Whereas, a considerable body of scientific evidence has accumulated since 2004 indicating that fish consumption during pregnancy can be highly beneficial to the nervous system of the developing fetus in spite of the presence of methylmercury, a known neurotoxin, in fish, and

Whereas, this evidence consistently indicates that eating at least two servings of fish per week or at least 12 ounces of fish per week can be more beneficial to the unborn child than eating less or eating no fish, and

Whereas, much of the fish consumption advice to pregnant women available today was developed before this scientific evidence became available and thus emphasizes limiting fish consumption in order to minimize risk from methylmercury without also taking into account the risk of loss of neurodevelopmental benefits, and

Whereas, as an apparent consequence of this older advice, there is strong evidence that fish consumption by pregnant women has declined to under 2 ounces per week on average and is lower for pregnant women than it is for young women generally, and

Whereas, the scientific evidence indicates that fish consumption this low during pregnancy is likely to be causing harm to unborn children in the United States, and

Whereas, in light of the evidence on the benefits of fish consumption to the developing nervous system, the U.S. Departments of Agriculture and Health and Human Services have issued Dietary Guidelines for Americans, 2010 that recommend that pregnant women considerably increase their consumption of most types of fish, and

Whereas, the salutary effects of this recommendation are jeopardized by the now-dated and inconsistent advice to pregnant women that was issued jointly by the U.S. Food and Drug Administration and the Environmental Protection Agency in 2004, and

Whereas, this inconsistency places a burden on state public health agencies on how to interpret the Federal advice and on how to advise their own citizens; therefore, be it

Resolved, that AFDO will request to FDA that it reconsider and update its fish consumption advice on a priority basis, in light of the science since 2004 and the new Dietary Guidelines for Americans.

RESOLUTION NUMBER 2

Submitted by: Charlene Bruce, President-AFDOSS, and Rita Johnson, Co-Chair for AFDO Seafood Committee, as submitted by the Seafood Committee member, Dr. Steve Otwell, Food Science & Human Nutrition Department, University of Florida

Date: May 2, 2011

Concerning: Public health advisories regarding seafood consumption

Whereas, the current and future supply of seafood consumed across the United States has significantly changed in the past five years and will henceforth differ from any prior decade such that the potential, calculated risks from mercury exposure through general seafood consumption in the USA will continue to be diminished, and

Whereas, numerous and recent formal position statements and group letters have been recently advanced by the Institute of Medicine of the National Academies (report issued 2007), by local and national professional organizations for public health and nutrition, by certain medical authorities and associations expressing concern for patients, and by many science-based conference proceedings about the nation and world, that are collectively calling for revised messages that can better direct healthful choices in available seafood, and

Whereas, national, state and local elected representatives from congressional and management agencies are calling for alignment of fish consumption advisories for public health, i.e, concurrent alignment with the new USDA Dietary Guidelines for Americans issued January 2011, and

Whereas, most of the current saturation of fish consumption advisories lack efforts or metrics to determine public health impacts or consumer utility and comprehension, and

Whereas, many messages and advisories do not clearly distinguish the more problematic choices from certain inland or freshwater sources that are more subject to recreational or subsistent consumption, and

Whereas, many current messages have significantly drifted from the original advisory issued jointly by EPA and FDA such that they create confusion and contradictions with additional avoidance categories, species identity, more toxins, and resource sustainability, and

Whereas, FDA is preparing a revised position on risk assessments regarding mercury and fish consumption for pregnant women, their children and women of child bearing years, therefore, be it

Resolved, that AFDO request FDA to inform respective state agencies with authority to develop and/or issue public health advisories for seafood consumption that they should reconsider the traditional approaches and incorporate considerations for all prior listed issues, and it be further

Resolved, that AFDO request FDA that they explore efforts through meetings, professional forums and materials to provide the most pertinent information to help support and monitor changes in advisories that are more current, useful and effective for public health.

RESOLUTION NUMBER 3

Submitted by: Charlene Bruce, President-AFDOSS, and Rita Johnson, Co-Chair for AFDO Seafood Committee, as submitted by the Florida Medical Association (FMA) c/o Dr. Todd LaRieu Sacks, MD, FACP (Jacksonville, FL)

Date: April 14, 2011

Concerning: The health benefits of fish consumption and dangers of mercury toxicity

Whereas, seafood consumption improves health. Seafood provides nutrients such as essential long-chain omega-3 fatty acids (DHA and EPA), vitamins, proteins, and minerals including iodine, iron and selenium, and

Whereas, peer-reviewed science has demonstrated for populations that the health benefits of eating seafood outweigh the risks, and

Whereas, for the expectant and nursing mother, seafood in the diet is the richest source of many nutrients that optimize the development of her baby's brain and nervous system. For infants and young children, nutrients contained in seafood are important for their optimal development and social behavior, and

Whereas, for adults, nutrients in seafood may help prevent or reduce coronary heart disease, stroke, psychiatric disorders, iodine deficiency, adverse effects of heavy metal exposure and possibly some cancers, and

Whereas, seafood consumption rates by Americans are among the lowest of all developed nations. The omega-3 fatty acid content of American breast milk is among the lowest in the world, and

Whereas, 2004 EPA-FDA fish consumption guidelines for pregnant women, lactating women and young children, which limits fish consumption to 2 meals per week (12 oz), is not supported by the more recent scientific evidence and consensus; the guidelines considered the risk, but not the health benefits of eating seafood, and

Whereas, methylmercury irreversibly inhibits selenium-dependent enzymes that the brain needs to protect itself against oxidative damage. Methylmercury exposure in excess of dietary selenium intake is potentially dangerous for women of child-bearing age, young children, or developing human fetuses, causing developmental disabilities in children, such as delayed walking, delayed speech, and decreased performance on tests of attention, fine motor function, language, visual-spatial abilities, and memory, and

Whereas, AFDO believes that seafood is a healthy food that should be a significant part of the diet of people of all ages except for the special concerns which exist for women of pregnancy age, infants, and small children due to the risk of toxicity from some fish species that contain high levels of mercury and low levels of selenium, or high levels of dioxin, therefore be it

Resolved, that the AFDO request the federal government to revise their current seafood consumption guidelines and advisories to emphasize the human health benefits of fish consumption for all age groups while also informing consumers of the risks to women of pregnancy age, infants, and small children of eating fish that contain high levels of mercury and low levels of selenium, or high levels of dioxin, and it be further

Resolved, that AFDO work with the federal agencies to share this information with its membership and other government officials.

RESOLUTION NUMBER 4

Submitted by: AFDO Board of Directors

Date: June 17, 2011

Concerning: The International Food Protection Training Institute (IFPTI)

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 how critical the training of state and local officials will be in advancing a national integrated food safety system, and

Whereas, AFDO and the Partnership for Food Protection (PFP) has previously identified the International Food Protection Training Institute (IFPTI) as the administrator of the training network for providing training to state and local food protection officials, and

Whereas, IFPTI has identified numerous trainers who are willing and able to participate in a development process to provide instruction in food protection training programs that have been identified as part of a recognized curriculum for food inspection staff, and

Whereas, state and local food protection programs are being evaluated by FDA to determine if their food inspection staff have been trained in accordance with this recognized curriculum, and

Whereas, IFPTI can provide standardized, career-spanning training of state and local food safety professionals to augment the inspection and surveillance capabilities of the Food and Drug Administration (FDA) and to assist FDA in meeting mandates of the Food Safety Modernization Act (FSMA), therefore, be it

Resolved, that AFDO write to FDA and advise the agency of AFDO's complete support for IFPTI and its ability to assist FDA in training federal, state, local, tribal, territorial, and industry officials, and be it further

Resolved, that AFDO requests FDA to meet with IFPTI to develop a strategy for training state and local officials.

RESOLUTION NUMBER 5

Submitted by: AFDO Seafood Committee

Date: June 20, 2011

Concerning: Formal request for FDA to continue partial support for the Seafood HACCP Alliance (SHA) for Education and Training

Whereas, the SHA has proven to be a very successful educational and training program assisting comprehension and implementation of FDA and State regulatory mandates for HACCP programs for seafood processing and commerce in the United States, and

Whereas, the SHA basic Seafood HACCP training programs are valued, respected and relied upon by both regulatory and commercial participants about our nation and the world, and

Whereas, the SHA has proven to be an integral educational component of AFDO's and FDA's cooperative alignment with the pertinent regulatory programs across every state and U.S. territory, the respective industry sectors from production through processing and retail operations, and the nation's network of academic experts addressing seafood safety, and

Whereas, the SHA has recently prepared new seafood HACCP training materials to complement and help explain the new, recently released (April 26, 2011) edition of FDA's Fish and Fishery Products Hazards and Controls Guidance, and

Whereas, the SHA is anticipating additional training support through annual Train-the-Trainer courses to assure a cadre of qualified instructors for both domestic and international audiences affecting commerce of seafood in the United States, and

Whereas, the SHA success has been based on cost-effective cooperation across existing academic and regulatory programs that can be leveraged to provide more cost-affordable training, and

Whereas, the SHA program is serving as a 'model' for development of similar food safety training programs for produce and other foods sold in the United States, therefore, be it

Resolved, that AFDO formally request continuation of partial support for basic SHA maintenance and infrastructure, to include the annual SHA Steering Committee meeting, based on existing funds that can be allocated for use through three years (2011-2014).

RESOLUTION NUMBER 6

Submitted by: Claudia Coles and David Read

Date: June 18, 2011

Concerning: State and Local Agencies Participation in FDA Hot Washes and After Action Reports

Whereas, the investigation of multijurisdictional foodborne illness outbreaks or environmental investigations, recalls, Reportable Food Registry Reports and all hazard emergency responses, such as the recent Gulf Oil Spill and the nuclear incident in Japan involves federal, state, and local jurisdictions collaboratively working together to quickly identify and resolve food safety issues, and

Whereas, the investigation and response to these incidents requires frequent communication and close cooperation, coordination, and collaboration of federal, state, and local agencies involved to quickly identify the implicated food products, and

Whereas, effective communication is a critical component of single and multi-agency incident response and investigation, and

Whereas, multijurisdictional food safety incidents require a multijurisdictional response to assess, control or prevent exposure risks and collaboration to develop and issue a united public message to educate and inform the industry and consumers, and

Whereas, holding after action meetings and conference calls or hot washes with the federal, state, and local participants, including industry as applicable, in multijurisdictional incidents is critical to identify gaps in the response and corrective actions, lessons learned, provide updates on the findings, conclusions and actions taken, and to document the actions taken in the After Action Report, and

Whereas, the Council to Improve Foodborne Outbreak Response (CIFOR) recommends organizations involved in multijurisdictional outbreaks should hold a conference call after the initial investigation ends to review lessons learned and to update participants on findings, conclusions, and actions taken; and

Whereas, Homeland Security Presidential Directive (HSPD) 5 states its purpose is “to enhance the ability of the United States to manage domestic incidents by establishing a single, comprehensive national incident management system” and the policy is “to prevent, prepare for, respond to, and recover from terrorist attacks, major disasters, and other emergencies, the United States Government shall establish a single, comprehensive approach to domestic incident management. The objective of the United States Government is to ensure that all levels of government across the Nation have the capability to work efficiently and effectively together, using a national approach to domestic incident management;” and

Whereas, mitigation strategies developed as a result of After Action Reports should be documented and implemented to minimize the impacts for future responses to incidents; therefore, be it

Resolved, that AFDO will request FDA to include all state and local participants in multijurisdictional food related incidents in conference calls and meetings or hot washes to identify and discuss lessons learned and provide information on findings, conclusions and actions taken.

2011 AFDO Position Statements



President

Ronald S. Klein
AK Dept of Env. Conservation
555 Cordova Street
Anchorage, AK 99501
(907) 269-7583
(907) 269-7510 FAX
ron.klein@alaska.gov

President-Elect

Oscar Garrison
GA Dept of Agriculture
19 Martin Luther King Jr. Drive
Capitol Square Room 306
Atlanta, GA 30334
(404) 656-3627
(404) 463-6428 FAX
oscar.garrison@agr.georgia.gov

Vice-President

Claudia Coles
WA Dept of Agriculture
1111 Washington St SE
Olympia, WA 98504
(360) 902-1905
(360) 902-2087 FAX
ccoles@agr.wa.gov

Secretary-Treasurer

Steven Moris
KS Dept of Agriculture
109 SW 9th Street, 3rd Floor
Topeka, KS 66612
(785) 296-5600
(785) 296-0673 FAX
Steve.Moris@kdaks.gov

Executive Director

J. Joseph Corby
Association of Food and Drug
Officials
2550 Kingston Road, Suite 311
York, PA 17402
(518) 860-2838
(717) 650-3650 FAX
jcorby@afdo.org

Association Manager

Denise C. Rooney
Association of Food and Drug
Officials
2550 Kingston Road
Suite 311
York, PA 17402
(717) 757-2888
(717) 650-3650 FAX
drooney@afdo.org

Association of Food and Drug Officials

2550 Kingston Road, Suite 311, York, PA 17402
Telephone (717) 757-2888 • Fax (717) 650-3650
E-Mail: afdo@afdo.org • Internet: www.afdo.org

May 16, 2011

Docket Clerk

U.S. Department of Agriculture (USDA)
Food Safety and Inspection Service (FSIS)
Room 2-2127 George Washington Carver Center
5601 Sunnyside Ave.
Beltsville, MD 20705

RE: Comments from the Association of Food and Drug Officials
Docket No. FSIS-2008-0031, "Mandatory Inspection of Catfish and
Catfish Products"

The Association of Food and Drug Officials (AFDO) is pleased to provide comments to the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS), regarding its proposed rule governing mandatory inspection of catfish and catfish products.

AFDO is the preeminent organization in the United States of federal, state and local regulatory officials, having promoted science-based food safety through the development of model laws and regulations, and providing uniform training over its 115-year history. AFDO is well-recognized for advocating a nationally-integrated food safety system that would reduce duplication and gaps which exist in the current system of regulating foods. AFDO has also expressed its concern for addressing food safety through a "piecemeal" approach where preventative controls are administered to a single food commodity or food sector rather than in a more broad fashion. It is from this perspective that AFDO is providing comments relative to the proposed rule.

The USDA/FSIS proposed rule is designed to ensure commercial catfish and catfish products are properly labeled, packaged, and are not adulterated. The proposed rule singles out domestic and imported catfish for regulation by FSIS under a "continuous inspection" program that is comparable to FSIS programs governing meat, poultry, and processed egg products.

The proposed rule would represent a shift in the regulatory oversight applied to commercial catfish production which will have a substantial impact on both domestic and foreign catfish and catfish producers. Affected producers would be subject to a greater regulatory burden in the form of continuous inspection, new recordkeeping requirements, and the pre-approval of labeling. AFDO does not believe catfish and catfish products pose unique food safety concerns which warrant producers of these products to adhere to these more stringent requirements. The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have both concluded that catfish and catfish products are a low-risk food, and FSIS has not provided any new information to date to affect that conclusion. Furthermore, there appears to be no existing rule which relieves FDA of its responsibility for regulating these products. The result is more fragmentation in the federal food safety system and the possibility of more duplication of effort. At a time when food safety resources are dwindling, this proposed rule seems very poorly timed.

115th Annual Educational Conference • June 18-22, 2011 • Dallas/Plano, TX

As the proposal is a required response to implement the 2008 Farm Bill, and absent any change or amendment to the law, mandatory inspection of catfish and catfish products will become a reality. Accordingly, AFDO provides the following specific comments to the proposed rule:

- 1) As AFDO views food safety system fragmentation as counterproductive, AFDO cannot support any further fragmentation to this system by exempting certain catfish species through definition. AFDO supports the application of the proposed rule to all fish of the order of *Siluriformes*.
- 2) AFDO does support the added scrutiny of imported catfish and catfish products, as AFDO does for all imported food. The same standards applied to domestic food production should likewise be applied to foreign-produced foods.
- 3) AFDO does not have any illness data to share, and AFDO relies on data provided by CDC, which indicates there have been seven (7) illness outbreaks since 1991 that may have been associated with catfish. Four (4) of these outbreaks were from retail establishments (restaurants or grocery deli), two (2) from a private home, and one (1) from a workplace where contributing factors such as temperature abuse, inadequate reheating, and poor sanitation were identified. Additionally, available data on chemical contamination, including FSIS' own sampling of catfish, does not, in AFDO's view, demonstrate a need for these regulations.
- 4) AFDO would recommend a definition for "slaughterhouse" be provided, as circumstances exist where catfish may have died under conditions other than the controlled circumstances of commercial processing. This definition could also clarify the possibility of processing "wild caught" catfish. This may not be necessary if only fish of the *Ictaluridae* family is subject to this rule but would most likely be necessary if all fish of the order *Siluroformes* are subject.
- 5) Exemptions generally cause interpretation problems among the various government agencies involved in food safety; therefore, AFDO recommends USDA/FSIS very clearly clarify all exemptions to this rule. While USDA/FSIS is considering applying its poultry exemption model, this model has not been without its problems. AFDO assumes that custom slaughter and processing will be exempt from resident inspection, provided the firm is operating under acceptable sanitation requirements. The retail exemptions for individual households (single sales of 75 lbs.) and non-households (150 lbs.) seem reasonable, although difficult to verify.
- 6) AFDO recommends the federal inspection brand be similar to the current brand for meat, poultry, and processed eggs, and that the processing facilities be numbered. AFDO does not support utilizing any special inspection brand for catfish.
- 7) It may be impractical to inspection stamp all carcasses of whole gutted catfish, and AFDO suggests other alternative measures be considered, such as branding master containers, affixing inspection lot tags, or marking invoices that accompany any shipments.
- 8) AFDO believes the appropriate regulatory approach for USDA/FSIS to employ with catfish and catfish products is the inspection verification system and not the command and control system. The verification system is similar to FDA's for all other seafood products.
- 9) Nearly all state food safety inspection programs are currently conducting Seafood HACCP inspections under contract for FDA. As is done with meat, poultry, and processed eggs, USDA/FSIS should develop Cooperative Agreements for state programs to conduct catfish and catfish products inspections.

AFDO is most appreciative of the opportunity to comment on the proposed regulations. Should you have additional questions or need clarification on any of the topics discussed herein, please do not hesitate to contact me.

Sincerely,



Ronald S. Klein
AFDO President

**President**

Ronald S. Klein
AK Dept of Env. Conservation
555 Cordova Street
Anchorage, AK 99501
(907) 269-7583
(907) 269-7510 FAX
ron.klein@alaska.gov

President-Elect

Oscar Garrison
GA Dept of Agriculture
19 Martin Luther King Jr. Drive
Capitol Square Room 306
Atlanta, GA 30334
(404) 656-3627
(404) 463-6428 FAX
oscar.garrison@agr.georgia.gov

Vice-President

Claudia Coles
WA Dept of Agriculture
1111 Washington St SE
Olympia, WA 98504
(360) 902-1905
(360) 902-2087 FAX
ccoles@agr.wa.gov

Secretary-Treasurer

Steven Morris
KS Dept of Agriculture
109 SW 9th Street, 3rd Floor
Topeka, KS 66612
(785) 296-5600
(785) 296-0673 FAX
Steve.Morris@ksda.ks.gov

Executive Director

J. Joseph Corby
Association of Food and Drug
Officials
2550 Kingston Road, Suite 311
York, PA 17402
(518) 860-2838
(717) 650-3650 FAX
jcorby@afdo.org

Association Manager

Denise C. Rooney
Association of Food and Drug
Officials
2550 Kingston Road
Suite 311
York, PA 17402
(717) 757-2888
(717) 650-3650 FAX
drooney@afdo.org

Association of Food and Drug Officials

2550 Kingston Road, Suite 311, York, PA 17402
Telephone (717) 757-2888 • Fax (717) 650-3650
E-Mail: afdo@afdo.org • Internet: www.afdo.org

May 20, 2011

Division of Dockets Management (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

RE: Comments from the Association of Food and Drug Officials
Docket No. FDA-2011-N-0259, "Periodic Review of Existing Regulations;
Retrospective Review Under E.O. 13563"

In accordance with Executive Order 13563, "Improving Regulation and Regulatory Review," the Food and Drug Administration (FDA) is conducting a review of its existing regulations to determine, in part, whether they can be made more effective in light of current public health needs and to take advantage of and support advances in innovation.

The Association of Food and Drug Officials (AFDO) is a non-profit professional organization consisting of state, federal, and local regulatory officials as members, with industry representatives participating as associate members. From its very inception over 115 years ago, AFDO has recognized the need for uniform laws and regulations and has actively promoted uniformity and cooperation among regulatory agencies at all levels. AFDO has also promoted the concept of a fully integrated food safety system for this country, which utilizes the resources and authorities of all levels of government as an effective means for meeting existing food safety challenges. FDA's wish to determine the effectiveness of current regulations appears to embrace this concept, and AFDO is pleased to offer its specific comments to this review as follows:

1. The FDA Food Code is the model regulation for retail food establishments. It is updated every four years through the Conference for Food Protection which permits insight from government, industry, consumer, and academic officials. The majority of food protection agencies have adopted at least a version of the FDA Food Code as their regulatory foundation for food safety for conducting food safety inspections at retail food establishments. While the concept of utilizing a model code as the recognized standard has been successful, for the most part, it does not remove the burdensome task of states promulgating new regulations through a time consuming process that includes hearings and scientific testimony. Generally, states cannot adopt a model code or "guideline" and can only use them as resource information. As a result, there are provisions of the FDA Food Code which do not exist in certain state regulations for retail food establishments. This lack of complete uniformity may occur as a result of industry lobbying efforts within a state or the lack of interest on behalf of the state food safety program to pursue specific code provisions. In addition, amendments to the Food Code occur more often than states care to go through their amendment process.

A more perfect scenario would be for FDA to codify the FDA Food Code, which would allow states to more easily promulgate it by reference. There is no impact on retail establishments to have a state requirement that is already a federal

115th Annual Educational Conference • June 18-22, 2011 • Dallas/Plano, TX

requirement. One must ask what regulations FDA enforces when they conduct retail food inspections such as during national or international events such as the Olympics or the Democratic and Republican National Conventions.

It is AFDO's strong belief that codifying the FDA Food Code would eventually result in uniform national standards and uniformity relating to retail food safety.

2. The states regulate interstate shipment of Grade "A" pasteurized dairy products through the Grade "A" Pasteurized Milk Ordinance (PMO). This requirement prohibits the distribution and sale of Grade "A" pasteurized dairy products from out-of-state sources unless that source has a verified preventative plan for food safety. While this system works well with domestically produced products, it does not for imported products as FDA does not restrict shipments of Grade "A" pasteurized products from foreign entities. As a result, states are left with the burden of either prohibiting the sale of these products within their states or traveling to these foreign countries for the purpose of verifying product acceptability. Some states have previously suggested that FDA should be the government entity to verify foreign Grade "A" pasteurized products.

Like the Model Food Code, the Grade "A" Pasteurized Milk Ordinance is updated every four years through the National Conference on Interstate Milk Shipments, which provides participation by government, industry, consumer, and academic officials. The federal adoption of the Grade "A" Pasteurized Milk Ordinance as a federal rule would remove the burdensome task of states promulgating new regulations through a time-consuming process that includes hearings and scientific testimony. Codification by FDA of the Grade "A" Pasteurized Milk Ordinance would allow states to more easily promulgate it by reference.

It is AFDO's opinion that FDA should take a more active role in this matter either by adopting the Grade "A" Pasteurized Milk Ordinance as a federal rule or by prohibiting the export of Grade A pasteurized dairy products into this country where verification has not been established.

AFDO believes uniform regulatory reform is necessary to advance a national integration strategy for addressing food safety issues, and enhancing consumer confidence in the safety of our food supply. These two measures would help to achieve these objectives as would a system of periodic review of regulations.

AFDO appreciates the opportunity to comment. Should you have additional questions or need clarification on any of the topics discussed herein, please do not hesitate to contact me.

Respectfully Submitted,



Ronald S. Klein
AFDO President

About the Authors

David W. K. Acheson, M.D., F.R.C.P., graduated from the University of London Medical School in 1980, and following training in internal medicine and infectious diseases in the United Kingdom, moved to the New England Medical Center and Tufts University in Boston in 1987. As an Associate Professor at Tufts University, he undertook basic molecular pathogenesis research on foodborne pathogens, especially Shiga toxin-producing *E. coli*.

In September 2002, Dr. Acheson became the Chief Medical Officer at the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition. Following several other positions at FDA he was appointed as Associate Commissioner for Foods, which gave him an agency-wide leadership role for all food and feed issues, including health promotion and nutrition.

In August 2009, Dr. Acheson took up a new position as the Managing Director for Food and Import Safety at Leavitt Partners LLC, a Consulting firm with offices in Salt Lake City and Washington DC. Leavitt Partners is working with a variety of multinational clients from the farm to retail to address food safety and food defense challenges.

Dr. Craig A. Kaml holds a doctor of education degree (Ed.D.) in Educational Leadership, with a higher education concentration, and an instructional technology elective, a master's of arts in education (Ed.M.) in Instructional Technology Specialist-Computers, both from East Carolina University, Greenville, North Carolina, and a bachelor's of science (BS) in Computer Information Systems from North Carolina Wesleyan College in Rocky Mount, North Carolina.

Since his honorable discharge from the United States Marine Corps, after having served a five year enlistment as an electronic technician, Dr. Kaml has progressively advanced through positions in the educational arena as a faculty technical support specialist at a community college, director of instructional technology at a small North Carolina state university, assistant director of distance learning at East Carolina University (the third largest North Carolina state university), director of the Distance Education Department, director of Academic Technology and Instructional Services, Associate Dean of Extended University Programs, and Interim Associate Provost of Extended University Programs at Western Michigan University. Dr. Kaml is currently serving as the Director of Curriculum Delivery for the International Food Protection Training Institute, in Battle Creek, Michigan.

Dr. Kaml's areas of professional interest and research include faculty development for distance education delivery, curriculum and instructional design, distance education administration, instructional (educational) technology, international educational partnerships (especially via distance education technologies and strategies), and the globalization of education.

Ron Klein, M.S., has completed his second term as President of the Association of Food and Drug Officials (AFDO). During his term he participated in the development of the International Food Protection Training Institute which offers career-spanning training for state and local food protection professionals in order to improve the overall protection of the U.S. food supply. He has served on the Board of Directors of the Western Association of Food and Drug Officials, on the Conference for Food Protection's Program Standards Committee, Food Safety Inspection Officer Work Group and Council II. He is an active participant in the Food and Drug Administration's (FDA) Partnership for Food Protection Coordinating Committee which is responsible for leading the development of an Integrated Food Safety System.

Mr. Klein recently retired from the State of Alaska where he managed the Food Safety and Sanitation Program, which provides food safety and environmental health services statewide consistent with those provided by state agricultural, health, and local government agencies. In 2010 in addition to his food safety responsibilities, he served as Acting Chief of the Alaska State Environmental Health Laboratory, which provides environmental analysis, food testing and veterinary diagnostic services for regulatory and research purposes.

Prior to becoming involved with food safety Klein had a diverse career managing air, water, and oil and terrestrial and marine hazardous substance spill assessment and cleanup programs in Alaska and has held leadership positions in associations linked with environmental regulatory programs. He has overseen diverse environmental projects including the cleanup of Alaska's pulp mills, assessing potential environmental impacts associated with the Amchitka Island nuclear test site, establishing national policies and guidance for the control of regional haze from wild land fires, supervised marine environmental assessments of the Southeast and South central Alaska coastlines and participated in Exxon Valdez Oil Spill Trustee Council activities. He has an M.S. in Forest Resources from the University of Washington and an M.S. in Environmental Quality Science from the University of Alaska.

Sarah Davis Ohlhorst started work with the Institute of Food Technologists in 2005 and currently serves as Research Scientist there. She holds a B.S. degree in human nutrition, foods and exercise with concentrations in consumer foods and dietetics, and a master's degree in foods from Virginia Polytechnic Institute and State University, where her thesis work focused on the effect of soy flour as a natural antioxidant against flaxseed rancidity in breads. She completed a yearlong dietetic internship with the Medical College of Virginia/Virginia Commonwealth University in 2002, and is a registered dietitian. She has co-authored several peer-reviewed publications, and is a member of the Institute of Food Technologists, the American Dietetic Association, and the American Society for Nutrition.

Sarah has numerous responsibilities at IFT, which include providing significant scientific/technical support on contract work with varied organizations such as The Micronutrient Initiative, the U.S. Food and Drug Administration, and the National Center for Food Protection and Defense in the areas of human nutrition and food safety and defense. She is currently leading tasks on a number of topics including this task for The Micronutrient Initiative to explore the use of iodized salt in processed foods.

Joseph Pickett is a freelance writer at www.josephmpickett.com. He is the owner of the pharmaceutical webinar website www.ExpertBriefings.com and contract lab job website Laboratory & Regulatory Retriever.

Cameron Prince is the Vice President, Operations Branch of the Canadian Food Inspection Agency, providing strategic leadership to the delivery of inspection and enforcement programs for the Canadian Food Inspection Agency.

Having held executive positions in both the Operations and Programs Branches in CFIA, Mr. Prince has gained a depth and breadth of knowledge and experience which serve him well in this challenging and multi-faceted role.

Mr. Prince has a Bachelor of Science Degree in Zoology (Honours) from the University of Western Ontario. He has been part of the Agency since its creation and has held such positions as Executive Director, Operations Coordination, Executive Director, Atlantic Operations and Executive Director, Animal Products Directorate.

Nancy Singer founded Compliance-Alliance LLC to specialize in the professional development for those employed in the medical device industry. Previously she served as AdvaMed's Special Counsel for FDA compliance and enforcement matters. In her role as Special Counsel, Nancy was a member of the FDA/industry working group that evaluated and suggested reforms to the FDA inspectional process. She then represented the industry on the working group that conceived and validated the procedures for the Quality System Inspection Technique (QSIT). She served as the industry spokesperson on the educational programs that taught QSIT to representatives of FDA and the medical device industry. While working on QSIT, Nancy received Vice President Gore's Reinventing Government Hammer Award and the FDA Commissioner's Special Citation.

Nancy began her career as an attorney with the United States Department of Justice where she did litigation for the Food and Drug Administration. Subsequently she was a partner at the law firm of Kleinfeld, Kaplan and Becker. Nancy received her B.S. from Cornell University, and J.D. and L.L.M. degrees from New York University Law School. During her career, she taught food and drug law at Catholic University Law School, George Washington University Law School and compliance symposia at Harvard University. She chaired the Food and Drug Law Section of the Federal Bar Association, and retired as a Commander in the United States Naval Reserve. Nancy's email address is nancy@compliance-alliance.com.

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

Gerald Wojtala is the Executive Director of the International Food Protection Training Institute (IFPTI) in Battle Creek, Michigan. IFPTI is a non-profit organization delivering career-spanning food protection training for state and local food protection professionals across the U.S.

Mr. Wojtala was the Deputy Director of the Food & Dairy Division of the Michigan Department of Agriculture (MDA) where he worked for 25 years. He had responsibilities for oversight of food safety, dairy, and food service programs in the State of Michigan.

Mr. Wojtala served as President of the Association of Food and Drug Officials (AFDO). AFDO is the premiere professional organization for regulatory food, drug and medical device officials from local, state and federal agencies. Mr. Wojtala is a long standing member of the Institute of Food Technologists (1994) and was a voting delegate to the National Conference on Food Protection. He is a member of the International Association of Food Protection, and the National Environmental Health Association. Mr. Wojtala earned a B.S. (1980) in Microbiology from Eastern Michigan University and has completed graduate courses in food science (1991) at Wayne State University.

President's Address
Ronald S. Klein, President
AFDO 115th Annual Educational Conference
Plano, TX -- June 19, 2011

It has been an honor and a privilege to serve AFDO as its president for the last two years. It has been an extraordinary time when we have been actively working on closing the institutional gaps in our food safety system while we continue to do our day-to-day jobs of ensuring the safety of food in commerce.

More than ten years ago, AFDO first advanced the vision of an integrated national food safety system. These efforts began in earnest during the last three years through the Partnership for Food Protection, which FDA implemented under the guise of a Strategic Vision for Food Safety. AFDO members played a key role from the start in their roles as federal, state, and local employees. During my first term, I had two officers and a board member move on to FDA to serve in leadership positions to help move food safety agencies toward integration. As a result, I was invited to stay on for another term to provide stability to AFDO as new officers were installed. Subsequently, two additional current board members moved on to FDA, along with other active AFDO members.

AFDO members also made significant achievements in developing elements which support an integrated food safety system. During the last two years AFDO members led the development of a Model Code for Produce Safety, began participating in the development of a new Produce Safety Alliance, updating and delivering training in support of the new Seafood Hazards Guide, played a key role in developing new guidelines through the Council for Improvement of Foodborne Outbreak Response, and proactively developed the community and support for the International Food Protection Training Institute.

On January 4, 2011, President Obama signed into law the Food Safety Modernization Act (FSMA) which established the statutory framework and expectation for realizing our collective vision. Collectively, we have to rise to the challenge of developing an integrated system against the backdrop of our responsibilities to protect public health on a day-to-day basis.

In the last two years we have seen the reinvigoration of the Drugs and Device section, which this year constitutes almost one third of the conference attendees. In recognition of the need to improve communication with drugs and device industry, we created an additional associate position to the Board to represent this important part of AFDO and help us put the "D" back into AFDO.

As a 115-year-old institution, we value our past, but we are also looking to the future. I would like to ask our first graduating class of IFPTI fellows to stand. They participated in a rigorous leadership development program mentored by many longtime members, and I look forward to them playing a key role in AFDO's future along with future graduating classes. I urge you to visit with them and view their research, which will be posted in the Trinity 2 room.

Thank you!

Glenn W. Kilpatrick Address
David W. K. Acheson, M.D., F.R.C.P., Managing Director
Food and Import Safety Practice
Leavitt Partners LLC
AFDO 115th Annual Educational Conference
Plano, TX -- June 19, 2011

(transcribed)

I can't tell you what a huge privilege it is to be asked to speak here today. In reference to the last speaker, I think one editorial comment about the "canaries", that group sitting over there (referring to the group of past AFDO presidents): I was trying to do a little math in my head and cumulatively those guys have got to have about 300 years of food safety experience, and I probably underestimated that. I don't see myself as a canary, so I'm afraid, guys, I'm just some old bird up here - not a canary.

When I was asked to do this talk, the request was: "just talk about what you want". Well, you know what that can mean. Telling someone like me to talk about what I want as an ex-regulator is really dangerous because, for the first time speaking at AFDO, I am not constrained as having to consider that I work for the "FDA." Now that I am in the private sector, watch out and fasten your seatbelts!

What I really want to do is talk about 3 things that I think are relevant at this point in time: new laws (FSMA), new outbreaks (Germany), and funds. To me, they are all interconnected. Let's start talking about FSMA and the fact that this is clearly groundbreaking new authority for the Food and Drug Administration. It is the biggest change in 75 years. It's massive; it's huge. If you track what's in that actual legislation, for those of us who have managed many of these outbreaks, at the local/state/federal level, you can see pieces of this new law based on situations going way to back to spinach, melamine, peanuts times 2, and a whole series of things – all feeding into the components that are in that new legislation. We're at a point where we have got an agency which has got massive new authority. The good news about that is it's heavily focused on prevention, and I think for years all of us in this game have said that reaction is real easy. It's not. It's really hard, as we all know, and it is long hours and hard work – but, relatively speaking, reaction is easy. The challenge is how you get out and prevent the problems in the first place.

That will link to my third theme which is funds, because when you are trying to be accountable that you are putting funds to good use and demonstrating you are making a difference, and then I've had people in Congress say "Ok, Dr. Acheson can you explain to me how you are counting the diseases you are preventing?" Think about it, it's not so easy. It's much easier to count the

deaths and the illnesses. So, the theme of the Food Safety Modernization Act is prevention. The second major theme of it, as I see it, is imports and challenges around imports. As we looked at the evolution of the time that I was at FDA and how the agency shifted from the focus on port-of-entry thinking, to the global food supply, and finally the regulators realized that the food industry had been worried about this for a long time, recognizing that as we have increased global sourcing, (Europe, South and Central America, Asia) and the threats and challenges around that. As I've got more involved with those in the private sector, I've come to see that these import issues and concerns are huge. These things are very concerning and, in fact, just last week, I was in Beijing and I had the opportunity again to hear how things are working there. One anecdote that I want to share with you on that trip is one of the lunchtime speakers was the gentleman who runs the Yum! Brands in China. Talk about a successful business model. He was talking about how Yum! is opening 500 new restaurants every year in China. He talked about Pizza Hut and he talked about Kentucky Fried Chicken, and the model is completely different, which I won't go into, but as he was talking, I was thinking "this is an interesting marketing strategy". I said to him, "It sounds to me like you are marketing food safety." He said, "Absolutely, we are, because in China people will go buy food because they see it is safe as compared to other places." I think subliminally we are doing that here, but it was a very interesting business model that he was moving towards successfully and blatantly to market - "we produce safe food, the guy down the street doesn't." It was as blatant as that.

So, as we begin to look at the FSMA and the challenge that regulators have at FDA in particular - and I had the delightful opportunity to meet some of my ex-FDA colleagues here this evening already - I know what a heavy lift that is with 50 or so guidances, regulations and reports to write over the next two years. It takes me back to when we were working on the Bioterrorism Act. I say "we" - I had nothing directly to do with it, but it makes me feel good to say that. That was essentially 2-3 years in the writing and that was a fraction of what the agency has got to accomplish with the FSMA. I applaud FDA for getting out there and hearing what people want to do. What do people think? Let's get input. Let's try to make this right, because it's a huge challenge.

So, as my first theme is the Food Safety Modernization Act and, as we think about that and link it into other key areas such as my second theme, which is outbreaks and response, FSMA ties into the importance of recognizing the value of an integrated food safety system. The gentleman who this talk is named after - Glenn Kilpatrick - as I was trying to understand his priorities (although I never met him), he was about integrated food safety systems. When I got to FDA looking at this and thinking "I got an idea," well no one has an original idea, clearly, but the importance of the local/state/federal and now I think foreign government players being part of working in integrating systems,

to the extent we can, is critical, but a big challenge. Part of this integration is training and, you know, I have the privilege to be able to work with IFPTI which is a model that I think has some fantastic success behind it. It's on a great trajectory. So in terms of the Food Safety Modernization Act, the integration, the building of these systems across the board, is going to be key.

The second point I want to make is around outbreaks. I would be surprised if there is a person in this room who has not lived an outbreak in some way or some extent or another either from the private side or from the public side or sometimes from both. I think as we have all gone through that, and obviously what is first and foremost in my mind today around outbreaks is the devastation in Europe that's happened in the last month. As Ron Klein said in my introduction, I spent 15 years' researching E. Coli O157 Shiga toxin producing E. Coli back in the late 80's going back to the original outbreak linked to ground beef in 1982. Until 'Jack in the Box' happened in 1993, nobody cared about this bug. It was in those years that we started to think about: this is not just E. Coli O157. You get a bug that can make toxin and could survive in food and stick to your intestinal wall, we don't care what coat it's wearing, whether it's a O157-coat or a O104-coat, it will kill you if it has the right virulence factors. That is the message we repeatedly tried to get over as an important public health message; it never resonated. Thankfully, we're now beginning to see people say, name the six we should worry about. If you look at those extra 6, well, O104 isn't one of them, so go figure if the logic of picking these six makes sense. Again, I told you I'd say things I can say in the private sector but couldn't say as a regulator, but to me it's completely illogical to be chasing 6 STEC when any STEC, if it gets the right set of virulence factors, can be deadly. Really, what we need is appropriate preventive controls that will address them all. If we look at this German outbreak, what can we learn from it? Number one, we absolutely can't be complacent here and say this is a European problem. This can happen tomorrow; it may even happen today, and we don't know about it yet.

As I was flying in here today, I was reading a blog from a very famous plaintiff attorney, who I'm sure you are all very familiar with, and he was talking about O169 and O103 related illness. I think he was in Tennessee. These other serotypes are happening, they are out there. So, lessons learned from this outbreak in Germany, as I am sure you are all watching it and you are all thinking, "Oh they got it, it's cucumbers. Oh no, it's tomatoes. Oh no, it's lettuce, or maybe it's sprouts." Believe me, I was sitting there sweating for these guys and thinking of how I got crucified on the Hill saying it was tomatoes when it was also from peppers. At least I didn't kill the lettuce industry at the same time. It's a massive challenge, and we all struggle with this dilemma as public health officials when there's illness going on that is as devastating as STEC, that can kill you, cause long term renal failure, results in kidney transplants, etc., and we don't want to wait 2 seconds longer than we have to

inform the public. So there's a constant dilemma. We don't know all of the facts, but we should warn people just in case, and when you're wrong you get crucified, which we've probably all felt. And when you are right, you feel good about it. This is a huge issue. When we look at the lessons learned here, I think the one part observing it, from the outside, reading the public information, is what I felt and what I suspect everyone else in this room felt: What are those epidemiologists doing? Why can't they figure this out? This is not 3 cases or 5 cases - this is 2,000 cases. What's with the case control studies? It's very easy to throw rocks from the outside, but what it does demonstrate, however much they were struggling, is the criticality of those local/state health departments for getting in there, asking the questions and figuring it out from the grassroots - once again emphasizing the importance of an integrated public health system.

That brings me on to my third theme, which is funding. Again, observing the world now from the private sector and looking at what has happened to the funding of food safety, it makes me very sad and, in fact, very worried about where this is headed. When I was with the FDA, we went through a period of very lean times in early 2001-2004, then things got pretty good and there was money that was coming in, and programs being built, and the concept of revitalizing the 50-State meeting and the Integrated Food Safety System. It was really starting to gain momentum and it was exciting, and now we are at a point where the agency (FDA) is given a huge task of the Food Safety Modernization Act - clearly essential - and at the same time, they are having their funding potentially cut. I recall being in hearings where Rosa DeLauro was chairing in The House saying to us as regulators, "I want to give you more money, but you have got to be accountable." That I applaud. Tell us how much money you want, how you are going to spend it, and how you are going to be accountable. That's key.

On the other side at the time, there was this 'FDA doesn't need any more money' and, unfortunately, that is what we are now seeing playing out today with a potential significant cut. We all know when you cut a program by 85 million dollars, the cuts go far deeper because of inflation and everything else simply barely keeps up. You need that as an increase to just simply stay in the same place. So an 85 million dollar cut is actually way more than just an 85 million dollar cut. It's a real hurt. So if you link these three things together, where we have got new legislation the likes of which we've never seen before, very exciting, very positive, huge potential public health gain; and we've got new bugs that are emerging that are highly pathogenic and very dangerous. We absolutely can't let our guard down with anybody who has anything to do with infectious diseases and public health and, at the same time, we got to do it for less. Somewhere there is a disconnect. From my personal perspective, I find that worrying; I'm concerned. I think one of the strengths that we have is that organizations like AFDO have the capacity to be able to begin to say we need to try to drive some change. We need to essentially band together and

show that this is not acceptable and demonstrate to decision-makers the consequences. So, while new authority is essential, and new authority is worthless without enforcement, enforcement doesn't happen without resources. What I'm worried about is, that three years down the road, people will say you've got all of this new authority and nothing's changed. Look at that Food Net data. It hasn't shifted much, especially for Salmonella. Well, you need money. You need resources. But you also have to have accountability. Another thing in the context of accountability and logic and money is, if we look at the disparity between the way our food safety agencies operate, and again I'm going to jump on the soapbox from a privileged position of speaking from the private sector, as a consultant I'll probably do myself out of jobs, but my point is when I look at the way FSIS operates with 7,500 establishments and about a billion dollars and compare it with the job that FDA has keeping track of 400,000 establishments with a little less than a billion dollars and half the number of inspectors, it just doesn't compute. Many will say the risks are different. I would argue no they're not; the risks are just as dangerous. Things can come out of nowhere, and we have got this massive disconnect. Where am I going with this? We need a single food safety agency. I could spend half an hour talking about that but I won't, because I realize I'm getting in between you and a glass of wine, and I'm going to get thrown off here pretty soon if I don't watch out. So, my point is, I can't let the funding notion go without acknowledging that we have still got this horrible (my word) disconnect in Washington between the regulatory agencies.

Now you can say we can just straighten out those going to regulate the pizza and so forth, but then they go and screw it up even more by introducing catfish. So you take one fish species away from an agency that's regulated seafood FOREVER, and you give it to another agency that says, yeah, we can do this. We can do it really well, but we'll need another 30 million dollars to do it right. Uh!

So where are the lessons in all of this? The lessons for me are that, yes, the agencies need this new authority, and FDA particularly needs the new authority. That's why I'm so happy to see this come through. I think industry has embraced it. For the first time in my career, there is significant legislation where essentially the bulk of the private sector, consumer organizations, and the regulators have all wanted the same thing. That's magical – and I don't use that term lightly, but it is magical. What I worry about is the funding of it. I think the notion of integrated systems, and this is not just state/tribal/local/federal - it's also the integration of the industry. IFPTI has an opportunity to begin to look at that, as do all of you, of saying, how can we work with our industry colleagues? This is not about making the best better; it's about bringing up the bottom-feeders so there is consistency in the system. I think as a final notion here, the one thing that I'd love us to be heading toward at some point in the future is a single food safety agency. It shouldn't

happen overnight; it needs to be done slowly and extremely carefully, but we cannot afford to continue to have this illogicity. At the end of the day, it warms my heart to see a group of state/local/tribal people here, along with their federal colleagues, and industry, and try to solve these problems when, as we heard earlier, that the lady over there contributed her dollar to a worthy cause, and she's about to get furloughed. What a mess, and it's very sad that we are in that state of affairs. So with that, hopefully 2-3 years from now, things will be on a better trajectory, but the fact that everyone has got here, on a positive vibe and with positive enthusiasm, about solving these public health challenges makes me feel really good, and I thank you for having me here to speak.

Thank you.

The Impact of the Food Safety Modernization Act on Federal-State Relations

**Michael R. Taylor, Deputy Commissioner for Foods
U.S. Food and Drug Administration**

It was a pleasure to attend your Annual Meeting in June. I always enjoy my interactions with AFDO and am proud of our good working relationship. AFDO members are key FDA partners and stakeholders and part of the coalition that is needed to implement the Food Safety Modernization Act (FSMA).

Of course, FDA was working with the States long before the new law was enacted. A fully integrated food safety system is a goal that we have shared for some time, and I believe we have made good progress through the Partnership for Food Protection. FDA has shown its support by funding contracts for inspections; establishing rapid response teams; and developing national standards, or models, for inspection, training, and certification.

The importance of partnerships in enabling us to succeed cannot be overemphasized. Our food supply is vast and complex and becoming more so every day. We have many actors involved, including government agencies, industry and consumers. Within government, we have numerous Federal agencies; state, local and tribal agencies; and foreign governments.

I see FDA and AFDO as a “team” that has a lot to gain by working together. In fact, FDA cannot succeed without the State and local governments as full operational partners. With the public’s high expectations and our finite resources, working as a “team” is no longer an option but a necessity. We must avoid duplication and use our resources in the best way possible.

I’m a bit of a baseball fan, as my co-workers will confirm, so I hope you will indulge me as I quote Babe Ruth. He said, “The way a team plays as a whole determines its success. You may have the greatest bunch of individual stars in the world, but if they don’t play together, the club won’t be worth a dime.”

The importance of working as a team is one reason why FSMA is so significant. It actually mandates – and creates a new accountability for – collaboration and integration and thus sets the stage for a new level of engagement.

With FSMA, we have a historic opportunity to build a food safety system that meets rising public expectations for safe food.

Prevention

For the first time, FDA has a legislative mandate to require risk-based, preventive controls across the food supply. Congress has singled out preventive controls as the fundamental framework of a food safety system based on prevention rather than reacting to problems once they occur. Prevention is not new, but Congress has given explicit authority to use the tool more broadly. The law also codifies that industry has the primary responsibility for prevention—Government doesn't grow, pack, transport or sell food—the industry does. It also requires FDA to set standards for produce safety and standards for intentional adulteration.

Inspection and Compliance

Within the preventive controls framework, FDA can carry out its appropriate responsibility more effectively. First, we'll set science-based standards for preventive control systems that industry must meet. Then we'll verify that industry is meeting them, using new tools to achieve high rates of compliance with the new standards. For the first time, we have mandated inspection frequencies for both domestic and foreign facilities, which we are linking with new ways to inspect. We have ready access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of the plans. And we have new enforcement tools, such as expanded administrative detention and suspension of registration and testing by accredited laboratories.

Import Safety

Import safety is perhaps the most groundbreaking shift in our new food safety law. The import provisions will help us address the growing number of imported foods in much more effective ways than relying as heavily as we must now on port-of-entry inspections. They are based on importer accountability and multiple means of verification to provide the assurances we seek.

Importers will be responsible for ensuring that their foreign suppliers have adequate preventive controls in place, and FDA will be able to rely on accredited third parties to certify that foreign food facilities meet U.S. requirements. The law also requires mandatory certification for high-risk foods, and it provides FDA with the authority to deny entry of a shipment if FDA access is denied at a foreign facility or by a country. I know these provisions are important to State and local agencies that receive overseas shipments.

Partnerships

Of course, FSMA emphasizes partnerships in all areas. The new law has three major categories of provisions that relate to Federal-State partnerships. First, FSMA emphasizes the need to rely on inspections conducted by other Federal, State or local agencies. Second, it emphasizes capacity building to enhance the food safety and defense capacities of State and local agencies. The law also requires FDA to conduct a survey of State and local capacities and needs for enhancement. The third area is training. FDA must set standards and administer training and education programs for State, local, territorial and tribal food safety officials.

FSMA Implementation

Implementation of FSMA is a daunting task because the issues are complex and they impose a huge new work load, but we are proceeding full steam ahead. Implementation is grounded in the same congruence of interests and ideas and sense of partnership that made the law a reality. Our principles for implementation have been to get the rules right, get the work done on a timely basis, and ensure that the prevention framework succeeds for the diversity of operations, including small businesses.

FDA has conducted, and will continue to conduct, extensive outreach to learn and foster dialogue among stakeholders—consumers, industry, and government. This is important in building consensus and strengthening the coalition needed for implementation. We are implementing FSMA with an unprecedented openness, transparency, and engagement with stakeholders across the board. Our goal has been to have active engagement before rules are written. We have held several public meetings, have accepted scores of speaking engagements and have an interactive web site with the latest news on FSMA (www.fda.gov/fsma). I can assure you that we will continue to work through the Partnership for Food Protection in the new FSMA framework to create an infrastructure for real integration.

We've made good progress so far on priority prevention standards. Preventive controls are familiar terrain, but it is a challenge to implement them comprehensively. Produce safety, on the other hand, is in many ways new terrain and a challenge because of the diversity of operations. With import oversight, there are many implementation challenges to build new systems and collaborate with foreign governments. Implementation will be a long-term process, not only because of the huge workload, but because we are building entirely new programs and systems and because tough issues will continue to arise even after the rules and new systems are in place. That is why we will maintain an open dialogue among stakeholders for the long term.

Resources are a challenge, and I know this affects the States significantly. We've been given a new set of jobs and a mandate to build a modern, new food safety system, but you can't build a new house without financing. We can put regulations on the books, but words on the page don't make food safer. To make them come to life, we need investment in science to understand hazards and preventive interventions in a dynamic environment. Meaningful implementation requires engagement with industry to share data and expertise and provide technical assistance, especially for small business. I'm preaching to the choir here, but we must invest in State and local capacity for both epidemiology and our regulatory partnership. We also must invest in import systems to provide adequate safety assurances.

With FSMA, we have a great opportunity to further the partnership between the FDA and state and local agencies. Federal-State integration has been a priority long before FSMA was enacted. But the new law facilitates us taking this integration to a new level. I look forward to working with all of you in the coming months and years as we take advantage of the opportunity to make the food supply as safe as it possibly can be.

CFIA Keynote
Cameron Prince, Vice President of Operations
Canadian Food Inspection Agency
AFDO 115th Annual Educational Conference
Plano, TX -- June 19, 2011

Good morning, everyone. My name is Cam Prince, and I am the VP of Operations at the Canadian Food Inspection Agency or CFIA. In Canada, we have one of the best food safety systems in the world. It is strong, and robust. In fact, Canada ranked fourth overall in a 2010 food safety performance ranking report that looked at 17 countries belonging to the Organisation for Economic Cooperation and Development (OECD). We were tied with the U.S.

While we always look for ways to improve, we start from a strong position. As all of you know, we operate in a very global environment. Canadians and Americans want foods from all over the world, and they want it all to be safe.

To give you a little history, the CFIA was created almost 14 years ago. As Canada's largest federal science-based regulator it is responsible for:

1. Programs to protect the safety of Canada's food supply – a jurisdiction and responsibility we share with some other federal departments such as Health Canada and the Public Health Agency of Canada. Of course, industry and consumers are key players in food safety as well.
2. We also deliver programs to protect Canada's animals, including livestock and aquatic species, from reportable diseases such as Avian Influenza.
3. Lastly, we provide services that protect Canada's plant resource base from regulated plant pests, and diseases. A good example of this is the work that we do to ensure that wood packaging remains pest free.

The CFIA has over 7,200 dedicated and highly trained professionals working across Canada. Aside from inspectors, we also employ scientists, lab technicians, veterinarians, lawyers, accountants and many other types of specialists.

The Agency regulates over 4,000 domestic food processing establishments, and oversees hundreds of thousands of domestic shipments of live animals, plant and forestry products, and tens of billions of dollars in annual import-export trade.

Since the time that the Agency was created in 1997, it has been responsible for administering and enforcing 13 different acts and their related regulations.

The Agency started with a sound regulatory foundation, and we have continued to maintain and strengthen the system. However, the intention in 1997 was for the Agency to consolidate and modernize its legislative base. For a number of reasons, Bills outlining new food safety legislation introduced to our Parliament were not passed. This is why legislative renewal will be a priority this year.

A rapidly changing environment is challenging us to update our legislative framework. The CFIA is being rightfully tasked to be more effective, responsive, streamlined, transparent and accountable to Canadians.

Legislative Modernization

To address our current and future challenges, our policy and regulatory affairs folks are working with the new government on possible new legislation. Once the recently re-elected government sets its agenda, we will have its direction with respect to any new legislative proposals.

However, I can say that the objective of any new food safety legislation would be to strengthen our ability to protect Canada's food supply and keep Canadians healthy, by modernizing and consolidating our existing food laws.

Canada's food safety system is based on legislation that is, in some cases, well over 50 years old. While food safety legislation has served Canadians well, it is time to update the requirements, tools and authorities to keep pace with the realities of the 21st century.

The CFIA was created, in large part, to strengthen consumer protection. There was a need, as well, to establish a more systematic approach to prevention and inspection. Advances are happening in safety systems and in inspection processes. Canada is seeking to integrate them into our risk-based inspection system.

Lifestyles are changing. Technology is changing food manufacturing processes. Canadians expect safe foods and demand innovative products. That is why new legislation is being considered. We need to provide the right tools so that Canadians can continue to rely on the effective protection the CFIA provides for both domestic and imported foods.

While the CFIA has demonstrated its ability to competently manage animal disease threats, such as mad cow disease (or BSE) and avian influenza, there have been other occasions when the expectations of Canadians were clearly not met. I am speaking of the listeriosis outbreak of 2008 when 23 Canadians died and many fell ill due to foodborne illness.

That tragic episode led Prime Minister Harper to name an independent investigator to find out how those events came to pass and what we needed to do to prevent it from happening again. The independent investigator's report made it clear that legislative renewal was necessary for the CFIA to fully meet its mandate and the expectations of Canadians.

The Government committed to addressing all 57 of the independent investigator's recommendations and the Agency is well along in meeting all of the issues raised in the investigator's report.

For now, I would like to take a few minutes to inform you of some possible areas that new legislation might address.

Canadian industry has long been requesting a provision prohibiting a person from tampering with, threatening to tamper with, or falsely claiming to tamper with products. They also want the Agency to directly address those who perpetrate hoaxes on the public. As we are all aware, hoaxes generate unnecessary public fear and can be economically devastating for producers. New legislation would allow the CFIA to aggressively pursue people who knowingly put hazardous foreign objects into food or who claim to have done so to generate public fear.

There is interest in greater authority to require tracking and tracing systems. New legislation could provide strengthened authorities in this area and provide the appropriate tools to take action on risky products when needed. Areas being considered include expanded authority to stop the sale of a product that may pose a risk to Canadians' health, or one that has been recalled. As you all well know, tracking and tracing systems, along with expanded requirements for record keeping, are critical in an age of global supply chains. The technology is readily available to provide effective traceability. We hope to leverage that.

There is also interest in providing for consistent inspection regimes for all food programs. Our current food safety regime has different inspection approaches for different kinds of foods, which can result in producers and processors reporting in inconsistent ways. In addition, the variation in inspection powers across different statutes is inefficient, costly, and difficult to administer.

The CFIA is working toward a system where all inspectors have consistent approaches across all food categories. With some inspectors covering multiple commodities, it makes sense to have one approach so they may do their job properly and efficiently. This can only promote the integrity of our food safety system to consumers and our trading partners.

Inspection Modernization Initiative

Getting back to some of my earlier comments about our variable inspection regimes for different food commodities, the CFIA continues to seek improvements to its current system. Although we have comprehensive protection, having different inspection processes for various food commodities means we aren't benefiting from economies of scale.

For the CFIA, a modernized inspection regime will improve the overall effectiveness and efficiency of CFIA as it will be managing inspection programs based on a single system. This will strengthen our risk-based decision making related to inspection frequency, inspection rigour, and resourcing across all commodities.

In terms of recruitment and training, a modernized inspection system will clarify the roles and responsibilities of the inspector of the future, for all programs, and all commodities. This, in turn, will guide the development and delivery of uniform inspector training modules.

Under the Modernized Inspection System, having one consistent approach will facilitate the ongoing process of modernizing information management and information technology systems. The goal is to implement improved systems that generate improved reports on the outcomes of our inspection programs and improved transparency for Canadians and trading partners.

Modernizing our inspection system will have clear benefit to Canadians, as we strengthen risk management and prevention controls. We know that emergencies will arise, and we will have to be responsive on these issues but having consistent and common processes will improve our responses to problems as they arise.

Canada/U.S. Shared Vision for Perimeter Security and Economic Competitiveness

On the topic of new initiatives, our two governments are also pursuing a significant one that would deliver efficiencies along our common border. A key new direction for Prime Minister Harper and President Obama is to establish a new long-term partnership that will enhance security and resilience against common threats while facilitating the flow of goods and people between both countries. The intended outcome will be job creation and economic growth through trade.

Our governments are looking for ways to reduce the cost of conducting legitimate business across the border by implementing, where it is practical, common practices and streamlined procedures for customs processing and regulatory compliance.

With Canada and the U.S. having such highly integrated markets, and many industries relying on complex cross-border supply chains, it is desirable that each country finds the means to smoothly align regulatory approaches while preserving high health, safety and environmental outcomes.

To promote and streamline legitimate trade, a Canada - U.S. Regulatory Cooperation Council (RCC) has been created, with a mandate to increase regulatory coordination and transparency between the two countries, for the ultimate benefit of consumers and businesses.

We should be hearing more about these initiatives soon as government working groups from the U.S. and Canada are expected to announce their Action Plans in the coming weeks.

Comparability

As both of our countries continue to deal with the challenges of a global recession, governments, of necessity, continue to look for ways to maintain or improve food safety outcomes while containing cost. Increasingly the principles of risk management will need to guide our thinking. Your country has brought forward the Food Safety Modernization Act, while Canada is executing on its Food and Consumer Safety Action Plan. Not surprisingly, both of these government initiatives are putting a special focus on food imports where, as we are all too aware, considerable vulnerability exists.

In Canada, consideration is being given to the licensing of importers. For example, Canada already licenses fish importers and is working on proposed regulations for licensing other importers, which would also include requirements for preventative food safety control systems.

Our two nations enjoy a long-standing trading relationship that is worth hundreds of billions of dollars a year. A very significant portion of that trade value is in food. If you only looked at trade volume and the variety of food being traded, you might conclude that considerable risk lay in this relationship. But the data do not bear that out. Non-compliance with food safety regulations is actually very low in terms of the food traded between Canada and the U.S. It, therefore, makes sense that both of our nations should be able to leverage that good record and that high degree of confidence in each other's food safety regimes so that we can focus more on where the risks are greater.

There was a time when "lot-by-lot" inspection was deemed the only way a country could ensure the safety of food imports. Clearly those days are gone. The volume of global trade makes that level of inspection resource prohibitive. While "lot-by-lot" still has value in certain circumstances, there are now other avenues open to us that achieve credible results with greater economy.

Many national regulators have implemented export certification for entire product categories, specific plants or particular producers. It seems a natural evolution that eventually we'll see "system recognition". System recognition acknowledges that while highly rigorous food safety regimes may be different from one country to another, the food safety outcomes are comparable. If two trading nations can achieve that kind of parity, it would make sense that they might be able to re-allocate some inspection resources to other areas of higher risk. Partnerships and collaboration were key provisions in the U.S. Food Safety Modernization Act, recently passed by your Congress.

Canada and the U.S. have a long history of collaboration in the area of food safety. Our food safety systems have evolved along similar lines, although within a different legislative framework. Both emphasize food safety as a public health goal. This history of collaboration, coupled with similar approaches and goals, mean we have a good basis for recognizing each other's systems and strengthening collaboration and information exchange.

Ethical Risk Profiling

On the topic of discipline, ethical performance and integrity in decision-making is also a sensitive and complex issue for all of us as regulators. It's something we take very seriously. We want our staff to understand that values and ethics should guide us to make the best possible decisions and use our own good judgment and common sense every day. We want them to commit to ensuring that our actions and decisions uphold the values of the Agency and conform to high ethical standards.

As regulators, we continually have to make decisions - inspection, product, enforcement decisions which are all based on risk. However, we also need to be aware of other types of risk, like risks to our integrity as a regulator. We must always be vigilant as staff may be pressured to compromise government rules or personal ethics by regulated parties. As we all know, it is a known vulnerability for all regulators.

The CFIA has always prided itself on the priority it places in values and ethics for all of our staff. And as part of an ongoing initiative, we are working with a Special Advisor to develop an Ethical Risk Profile (ERP). This ERP will promote Agency integrity, by identifying and measuring the potential for ethical risks. It also includes a strategy to reduce or minimize these risks. This initiative will provide employees with information on the causes, consequences and options for addressing ethical risks, especially those risks that could potentially harm program delivery.

We are now in the process of communicating the ERP to our stakeholders, in addition to further discussions with managers and staff. The result will enhance Agency transparency and people's general understanding of our activities.

Transparency

Further on the topic of transparency, consumers and consumer groups have been pretty consistent in telling us that they want more information on inspection, compliance and enforcement activities that promote the safety of our food supply.

Similar to initiatives undertaken by the U.S. FDA, Canada is also taking action to deliver on that expectation.

We agree that Canadians should have more information when regulated parties are not compliant with regulations. To provide that information, the CFIA has begun publishing information on its compliance and enforcement activities on its website. It is also available through the Government of Canada's food safety web portal.

To start, the CFIA is providing quarterly statistics on food imports that have been refused entry into Canada. We will also publish other information such as:

- The confiscation of food products that could not be brought into compliance;
- Federally-registered food establishments whose licenses have been suspended, cancelled or reinstated; and
- The names of repeat violators who have received Notices of Violations with Penalty in the course of carrying out their business.

As this initiative expands, Canadians can expect to see even more information about enforcement and compliance being made available to the public.

Canadians expect the Canadian Food Inspection Agency to deliver on its mandate in an open and accountable way. At the same time, the CFIA continues to work closely with the food industry to ensure they have clear guidance on how to achieve that compliance.

There is a demonstrated public need and interest for this type of disclosure. It is also consistent with information that is already publicly shared by other federal regulators both in Canada and the U.S.

We believe that making this information public is a fair, balanced and measured approach to protecting the safety of Canada's food supply and the resources upon which it depends. And ultimately, it protects the good reputation of Canada's food industry both here in Canada and around the world.

I'd like to thank you all for your time today. What I hope to have communicated with all of this is that we share many of the same issues – and the largest unprotected border in the world. These types of meetings are very important so that we can share best practices and provide better protection to our people on a continental level. I believe we are making great strides toward that through meetings such as this.

Thank you very much.

Product Tracing in Food Systems: The Institute of Food Technologists' Recommendations to FDA

Sarah Davis Ohlhorst, MS, RD, Staff Scientist

The Institute of Food Technologists

AFDO 114th Annual Educational Conference

Norfolk, VA -- June 19, 2010

The Institute of Food Technologists (IFT) is a not-for-profit scientific and professional society with over 18,000 individual members who work in food science and technology and related fields throughout government, academia, and industry. IFT's world headquarters is located in Chicago IL, and a second, smaller office is located in Washington, DC. The majority of IFT's contract and grant work is conducted from Washington, DC. Since 1999, IFT has held three five-year contracts with the U.S. Food and Drug Administration related to food defense and food safety. IFT, under contract with FDA's Center for Food Safety and Applied Nutrition (CFSAN), convened a panel of experts to examine available technologies and current product tracing practices in food and other industries in October 2008. In June 2009, FDA's Office of the Commissioner also commissioned IFT to conduct a mock trace-back/trace forward of the tomato supply chain with various partners. Both tasks were submitted to FDA in September 2009 via final reports with product tracing recommendations.

Product tracing is the ability to follow a product's movements through the various stages of production, processing and distribution. Product tracing has many economic and public health impacts since the ability to trace food forward may prevent further sale and consumption of a contaminated product, while the ability to trace food back may help to determine the cause of the issue and prevent it from happening again in the future. Therefore, effective product tracing throughout the farm-to-fork supply chain is of key importance in improving the speed and efficiency of response following a food safety triggering event, shortening the duration of foodborne outbreaks, and contributing to the maintenance of consumer confidence. The cost of ineffective product tracing for both industry and society can be in the billions of dollars.

The extensive scope of IFT's product tracing task (which was referred to as Task Order #6) was to identify current and future product tracing systems, both in the United States and abroad, in use in the food industry, as well as in other industries such as the parcel/postage industry. IFT examined product tracing for the entire farm-to-fork chain - from harvest through processing and distribution to points of service, so beyond the scope of the Bioterrorism Act of 2002 which exempts farms, restaurants, and others from one-step up and back recordkeeping. FDA also requested that IFT focus on produce but still include

other FDA-regulated food products for this task. IFT determined the accessibility of product tracing information to public health regulatory officials, and their product tracing information needs in developing our recommendations. IFT also considered the cost of product tracing to companies as part of this task, but in a separate report to FDA.

IFT put together a distinguished, core Expert Panel of 8 individuals who are familiar with various aspects of product tracing to assist with developing recommendations for this task. IFT also enlisted the help of multiple subpanels for this task, with expertise in the areas of state trace-back investigations, the food industry, agricultural economics, and technology. IFT spoke with over 200 stakeholders throughout this task to garner more information on product tracing, including representatives from over 55 companies of various sizes and in different sectors throughout the farm-to-fork supply chain, several trade associations, consumer groups, and about a dozen product tracing technology providers. Although these numbers are not representative of the entire food industry, given that IFT only had a year to conduct a task of this scope, staff spoke with as many stakeholders as possible to get an accurate representation of product tracing practices. Stakeholders helped IFT to gather information on what product tracing systems and technologies are available or in development, how other industries trace their products, product tracing requirements in other countries, how food companies currently trace products and how they could improve upon those practices, and finally, the cost to implement product tracing best practices throughout the entire farm-to-fork supply chain.

IFT's investigation of currently available or in development product tracing systems and technologies found that there are primarily three main categories of solutions providers: providers of software as a service; providers of a medium or unique identifier for companies to trace products with, and providers of cold chain management, or other quality and safety-related services. Existing technologies that may be adapted to capture key data elements useful for product tracing include accounting, batching, and warehouse management systems (WMS). Some companies also utilize custom-made software programs or have legacy in-house programs in place that can be adapted to capture key product tracing data.

The other industries where product tracing is utilized that IFT examined include the automotive, pharmaceutical, toy, parcel, clothing, and appliance industries, as well as the animal identification system utilized by the U.S. Department of Agriculture. IFT found that other industries may implement product tracing for reasons such as to avoid counterfeiting, to prevent animal disease outbreaks, due to high cost of the product, and so on. IFT explored Codex Alimentarius and ISO standards and documents for existing product tracing best practices, as well as requirements in various developed regions around the world, including

the European Union, Australia, and Canada. IFT also found that other countries may implement product tracing for reasons other than the U.S., such as to determine country of origin and the use of GMOs or biotechnology in foods. Less developed regions of the world may lack a regulatory structure to implement food safety requirements, including product tracing. There are also private product tracing initiatives in place that IFT investigated. This researched yielded several key findings:

- Food production is complex and global, which can make product tracing difficult.
- The technology to trace food products exists and continues to evolve. It is important to note that IFT's work represents a snapshot in time and that technologies and product tracing initiatives have likely continued to evolve since September 2009.
- Many food companies that IFT spoke with believe their recordkeeping is in compliance of the 2002 Bioterrorism Act (maintain one-step up and back records); however, the lack of common data elements for product tracing throughout the supply chain may not allow complete product tracing.
- Companies typically record product received and who shipped it and who they ship product to (one-step up and back records), but there is limited internal tracing at companies to match what is received with what is shipped.
- Paper recordkeeping is the predominant form of recordkeeping used by most food companies today – at least at some point in their system.
- Many sectors of the food industry have their own product tracing initiatives to ensure complete product tracing within a sector.
- Reported costs of product tracing vary greatly and often were inaccurately estimated.

Several issues that may prevent product tracing were identified by IFT during our research, such as the fact that paperwork generally lacks complete information to aid in product tracing. No standards currently exist for the entire farm-to-fork supply chain to capture product tracing data that would aid in complete and accurate product tracing. Since there are no standards companies receive different information from each different supplier, and they must provide different information to each customer. There is also confusion around the term "lot" – it means different things to each company, and internal tracing can be hindered since the lot received may differ from the batch lot or the lot shipped and records showing the relationships between what is received and what is shipped may not be adequate. Internal tracing may also be hindered because within a facility different internal systems are often used which may not be electronically linked and are therefore not interoperable, or able to share information easily with one another.

Some barriers to product tracing that IFT identified were: suppliers don't routinely provide information conducive to product tracing, yet customers often expect their suppliers to keep all records necessary for product tracing and don't consider themselves responsible; it is difficult to track bulk products because of commingling of various lots; there is a lack of data sharing standards; and the perceived high or added cost of product tracing. Some motivators to improved product tracing were: the fear of regulation or imposed standards if product tracing was not voluntarily undertaken; the improvement of other processes, such as inventory control, and the improvement and/or maintenance of consumer confidence in addition to improved product tracing. Others felt any costs incurred to improve product tracing were just the "cost to do business."

Accurate product tracing impacts regulators in that it allows them to more quickly locate the source of contamination and determine the scope of the problem. Without product tracing the cause often cannot be easily or quickly determined and consumer exposure to contaminated product will continue to broaden, causing increased public health costs and costs to the food company(ies) responsible. The food company, brand, or even product category's reputation may also continue to be damaged. Accurate product tracing may allow for more targeted advice to consumers and for more targeted recalls, and may eliminate the need for multiple recalls after an initial recall. Product tracing standards may eliminate current gaps in product tracing recordkeeping by requiring all points in the farm-to-fork chain to maintain records and may detail what must be recorded in those records.

Based on extensive research, IFT and the Expert Panel recommended Guiding Criteria for product tracing systems undertaken by companies or governments. Standardized ways to express data necessary for product tracing could help to ensure that all of these criteria be met. It should be simple and user friendly for all to understand and participate in; it should leverage existing industry systems to control costs and again, increase the likelihood of adoption; and it should be globally accepted since the food supply is global. As an example of the complicated and global food supply, the National Center for Food Protection and Defense examined a cheeseburger – beef, bun, cheese, pickles, lettuce, onion, grill seasoning, and sauce – to determine that it had over 75 ingredients that may have come from numerous countries. One ingredient, vinegar, alone has elements that may be sourced from over 30 countries. IFT felt that the medium of information transfer was far less important than the information required for product tracing. Therefore, although we reported on differences between RFID and barcodes, one was not recommended over the other. It's much more important that the data carried be correct for accurate product tracing.

IFT's core recommendations for product tracing are to identify Critical Tracking Events (CTEs) representing each time the product is moved, transformed, or so on. CTEs are similar to Hazard Analysis and Critical Control Points (HACCP) which is widely used throughout the food industry today, except CTEs are points critical to accurate product tracing. For example, a foodservice supply chain has identified their CTEs to be shipping, receipt, and each time a case is opened or closed. IFT also believes product tracing should be at the case level, since the term lot has no standardized definition and is used differently throughout the industry. Records must be kept for every CTE in an agreed upon, standardized format that is able to link incoming ingredients or products with outgoing ingredients or products for accurate internal tracing. All firms in the entire farm-to-fork chain must be able to provide key data elements (KDEs) for all CTEs in an electronic format within 24 hours of a request from a regulatory agency. KDEs may include lot number, date, company name, and so on. Although IFT did not feel it necessary for companies to only use electronic records, it is necessary for the company or a 3rd party to transfer all records to an electronic format in a timely manner since electronic records can be shared more quickly and easily, and data analysis is substantially facilitated. Even if product tracing recommendations are perfectly written, we'll be no better off if people aren't aware of them or don't comply. Training and education on CTEs and KDEs must be developed and implemented, and product tracing should become a required part of regulatory or 3rd party audits.

In a second report to FDA, IFT examined the costs of product tracing and found that firm's generally could not provide estimates of the cost to implement improved product tracing, although they frequently suggested it was expensive. Firms' frequently assigned costs to product tracing when in reality it was not a cost for product tracing, but for something else such as inventory control. IFT was not able to find very much data on costs of product tracing other than a very few case studies that have been conducted. Costs associated with improved product tracing may include capital investment and start up fees, software and associated fees, equipment, consultants, labor and training, materials and supplies, and the cost of a change in operations. Benefits of improved product tracing might include improved supply chain management, better inventory control, increased access to contracts and markets, as well as more targeted recalls.

Costs of poor or no product tracing to society may include increased healthcare costs due to a higher incidence of illness and loss of life, a loss of consumer confidence, major psychological and emotional damages due to many massive foodborne outbreaks, and the indirect loss in economic output and productivity losses to companies. Loss of market share may result if traceability systems are not similar for whole sector. Also a lack of adequate capital, labor, and technology expertise can make it difficult to implement product tracing. IFT

felt that the probability of the occurrence of a triggering event per year versus the costs and benefits per sector needs to be further assessed.

IFT also conducted another product tracing task to conduct a mock trace-back/trace forward of tomatoes using a complete existing supply chain data set and visualization software. Tomatoes had been selected for this task due to the complex 2008 *Salmonella* saintpaul outbreak. IFT subcontracted with Harvard, Microsoft, and TIBCO on this task, and FDA and members of the tomato supply chain also participated. IFT's portion of the task was to compare the visualization software with other existing or planned product tracing technologies. The comparison was done on a number of different factors, such as the ability of each platform to store data, including how much and for how long; data management; accepted formats of data; how data are shared and accessed; and so on.

Members of the tomato supply chain provided existing data collected from a period in November 2008. This task did not explore how data would be collected in real time if this pilot were to move to fruition; non-disclosure agreements were required by some companies just for this pilot. Other challenges included a lack of real time data, only one food product, a limited geographical region lacking import data, and a limited supply chain. The quality assurance of the data for this task was substantial since data were submitted in non-standardized formats. This task showed that identification and evaluation of key data elements and standardized data are necessary for product tracing. The visualization software showed the potential to expedite trace-backs/trace forwards by finding points of commonality in the visualized data, very dependent on data availability, capture, and readiness. IFT's comparison showed that there are many commercially available systems that could potentially also expedite trace-backs/forwards using these data. This task ultimately showed that communication and collaboration among supply chain partners and among industry and government are very valuable to product tracing.

IFT's full reports on product tracing can be found online at ift.org/traceability. Many industry initiatives on product tracing are underway and the technology to trace continues to evolve. FDA and USDA FSIS collected public comments and held a meeting in late 2009 on the topic, where IFT was asked to comment twice on our product tracing work and IFT also submitted public comments. Many are now awaiting impending food safety legislation to see what the future holds for product tracing. IFT recommends clear objectives be set for all members of the food supply chain, allowing the food industry flexibility in determining how best to reach those objectives, and anticipating that technologies to reach these objectives will continue to improve.

Elements of the IFPTI Training System

By Craig Kaml, Ed.D. and Gerald Wojtala

International Food Protection Training Institute (IFPTI)

The FDA Food Safety Modernization Act (FSMA) marked the most significant change in U.S. food safety law in over 73 years. The FSMA validates FDA efforts for integrating the U.S. food safety system to build capacity and leverage the resources of government at all levels. IFPTI is assisting FDA in meeting the requirements of this law and achieving the goal of fully integrating the food safety system and ultimately providing better protection of the food supply. Training the tens of thousands of food protection personnel across the U.S. to measurable standards assures competency and comparability so that all stakeholders can rely on any regulatory inspection, investigation, laboratory analysis, or emergency response.

A public health, risk-driven, evidenced-based, integrated food safety system that focuses on preventing harm before it happens is dependent upon the development and implementation of training and certification programs. This is to achieve a high level of scientific quality in data collection and inspections; ensure uniform and consistent approaches to food safety throughout the national system; and help build capacity across state and local agencies. Working with the FDA and leveraging the work being done by the Partnership for Food Protection (PFP) Training Work Group and FSMA implementation groups, IFPTI seeks to develop a national work plan for the delivery of blended classroom and web-based courses to improve the quality of inspections, investigations, sample collections and analyses, enforcement, emergency response and recovery activities, communication, and outreach; with the performance of competency assessments consistent with a framework for certification to be developed by the FDA.

IFPTI is uniquely positioned to address the needs for the creation of a training program for an integrated food safety system. IFPTI has created a curriculum framework for an integrated food safety system; cataloged more than 700 existing U.S. food safety courses; created a process to apply ANSI and IACET course quality standards through the review of existing courses and development of new courses; utilized a backmapping process to align outcomes-based training with identified job tasks; implemented an established instructor development and management system; created and used an evaluation logic model to ensure quality; established systems to support registrar functions; and incorporated training offered by providers across the U.S. to offer needed training to food protection professionals.

The components of the IFPTI training system include: 1) curriculum framework; 2) existing course inventory; 3) course standards; 4) instructional design process; 5) course development; 6) instructor development; 7) instructor management; 8) Course delivery; 9) Registrar function and on-line learning system; 10) JTA alignment/backmapping process; 11) an evaluation logic model; 12) serving as central administrator of a nine-member consortium of university training centers; and 13) the establishment of a national training research council.

1. **Curriculum Framework:** IFPTI has developed a career-spanning, standards- and competency-based, curriculum framework for an integrated food safety system.

The curriculum framework consists of four professional levels (entry, journey, technical, and leadership), each containing three professional tracks (unprocessed, manufactured, and retail). The framework was designed to demonstrate the interrelationship between, among, and progression through, four professional levels as well as to represent content areas within the professional levels and tracks. Levels and tracks are further divided into content areas, which contain courses arranged in sequential order to provide learning paths within the content areas. The curriculum framework includes programs designed to span various professional levels (e.g., the Fellowship in Food Protection, which spans journey and technical professional levels).

This competency-based and standards-based, career-spanning curriculum framework and the curriculum development process constitute significant advancements in the field of professional development. The first-of-its-kind curriculum development process initiated by IFPTI is being documented for publication in peer-reviewed education journals.

IFPTI formed a curriculum team consisting of a diverse group of state and local officials, academicians, and FDA staff, who worked collaboratively to create the curriculum framework. To date, the team has completed these objectives:

- a. Determined the journey-level core and main specialty content areas of the curriculum framework, which contains approximately 100 content areas.
- b. Identified and validated general and technical competencies.
- c. Mapped competencies to framework content areas.
- d. Reviewed existing courses for fit within IFPTI curriculum framework.
- e. Mapped existing courses into the framework.
- f. Identified potential certificate programs.
- g. Mapped courses into certificate programs.

- h. Determined the journey-level core content area training course gaps.
- i. Identified potential courses for core content areas gaps.
- j. Identified scope and topics within potential journey-level core content area courses.

The curriculum team will continue to perform work to sequence courses within content areas, prioritize new course development, review existing courses for IFPTI course standards, establish an existing course improvement process, and map working competencies to existing courses. The curriculum team will collaborate with the FDA on the technical and leadership levels. The curriculum team will also collaborate as needed with the FDA on the Office of Regulatory Affairs University (ORAU) online entry-level courses.

2. **Existing Course Inventory:** Establish and maintain a food safety training course inventory comprised of courses available throughout the U.S. and its territories.

IFPTI completed an inventory and classification of over 700 existing food protection training courses in the U.S. in order to assess gaps and course placement into the national curriculum. The inventory in the Food Protection Course Catalog represents the known food safety-related training or educational courses currently in circulation. This catalog is a starting point in developing a curriculum for food protection officials in an integrated food safety system as identified in FDA's training vision. The IFPTI curriculum team continues to review each course in the inventory for categorization, placement in the curriculum, and quality indicators.

3. **Course Standards:** Review of new and existing food safety training courses against instructional design and delivery of ANSI/IACET quality standards.

IFPTI has developed a course review acceptance process for reviewing existing and proposed courses for fit within the curriculum. Course quality standards have been identified through IACET and ANSI. IFPTI has developed a set of quality practices that comply with ANSI/IACET 1-2007 Standard for Continuing Education and Training. This standard provides a framework that will enable IFPTI to adhere to quality continuous education and training practices. The steps undertaken by IFPTI in compliance with this standard enable the organization to establish appropriate responsibility and control systems; take an analytic approach to identifying and analyzing learning needs; design, plan, and provide quality learning events; establish appropriate assessment criteria based on the learning outcomes; and monitor and improve the learning process in order to achieve learning objectives.

IFPTI has established evaluation and assessment efforts to measure learning outcomes. Overall, the IFPTI logic model delineates outcome paths. Developed tasks include:

- a. Application and compliance with ANSI Certificate requirements for the IFPTI Fellowship program.
- b. Documentation of individual and collective course delivery evaluation process.
- c. Implementation of the process for longer-term follow-up on student learning/retention and application of course material.
- d. Establishment of a course development process where other course owners would comply with a review for adherence to the inclusion of evaluation components in those courses.
- e. Identification of metrics for various IFPTI development and delivery initiatives.
- f. Monitoring of the FDA and Centers for Disease Control and Prevention (CDC) national performance metrics development efforts.
- g. Assessment of the IFPTI application of objectives to the DHHS Healthy People 2020 goals.

4. **Instructional Design:** Application of an analysis, design, development, implementation, and evaluation (ADDIE) instructional design process and ANSI/IACET quality standards to the development of food safety courses.

IFPTI uses an iterative outcomes-based ADDIE instructional system design process collaborating with subject matter experts to create course concept and design maps. Content is parsed into manageable segments based on adult learning theory through a concept mapping process, providing a blueprint for course development based on ANSI and IACET guidelines.

All courses and course modules are defined within a content alignment planning documentation (CAPD), articulating written scopes (defining overall goal of the course or module), terminal and enabling learning objectives, and content alignment to identified competencies. Courses are designed for appropriate levels of Bloom's Taxonomy (http://en.wikipedia.org/wiki/Bloom%27s_Taxonomy) to address expected knowledge, skills, and abilities outcomes, building in assessment and evaluation based on the Kirkpatrick training evaluation model (Kirkpatrick Partners). All courses designed and developed by IFPTI are intended for inclusion in the national curriculum for an integrated food safety system.

5. **Course Development:** Implementation of course development theory, methodologies, and practices.

Once courses are identified as priorities for the build-out of the IFSS curriculum, the course development phase begins. IFPTI uses an iterative

design process working with subject matter experts who provide formative feedback on rapid prototypes of course materials and content delivery methods. IFPTI staff members work with subject matter experts to write course elements such as scopes, competencies, terminal and enabling learning objectives, and assessment questions for modules and courses. The course elements are compiled in content alignment and course alignment planning documents to ensure that ANSI and IACET quality standards are met. Curriculum development meetings are scheduled prior to the pilot course as needed to ensure a consistent development process that aligns with the curriculum framework as set forth by the curriculum team and the Director of Curriculum Development and Delivery. At these meetings, guiding principles and philosophies are discussed and clarified to ensure that subject matter experts write course materials using Bloom's Taxonomy, the Kirkpatrick evaluation model, and the IFPTI standard design process (specifically ADDIE). For example, course elements are designed with the end evaluation process in mind as a means of ensuring that participants meet learning objectives, and that courses are developed that produce quantifiable and measurable results.

Once course materials and delivery methodologies (in-person, online, or blended-learning) are solidified, a pilot test of the course is conducted to assess course content alignment with the curriculum design map. Formative and summative feedback is used to make content and course corrections or modifications as necessary. Evaluation (participant and program) analysis is reviewed during debrief meetings to ascertain where course corrections or modifications are indicated. These course corrections or modifications are then made during follow-up course redevelopment meetings conducted on-site and online to collaborate with subject matter experts nationwide.

Throughout the course development process, IFPTI staff incorporates the use of a Learning Management System (LMS) to maximize the use of available technologies and to increase in-house efficiency by making courses scalable.

The course development staff and SMEs are currently in the process of updating FDA's FD170: Application of the Basics of Inspection and Investigation course. Ongoing communication and site visits between IFPTI and FDA's ORA-U ensure that the efforts of both organizations complement one another in the joint task of implementing the mandates of the recently passed Food Safety Modernization Act (FSMA). IFPTI staff members are currently working to add increased functionality to the IFPTI LMS by means of adding a secure self-registration feature for approved participants to the IFPTI website. The course development team (staff and

SMEs) is also actively implementing improvements for the second cohort of the Fellowship in Food Protection program, based on knowledge gained during the evaluation process after the first year.

6. Instructor Development: Establishment and implementation of a food safety instructor development, evaluation, and management process.

IFPTI developed a process to identify individuals in the food protection community interested in becoming qualified instructors and subject matter experts.

IFPTI recruits experienced food protection professionals to become qualified instructors. Individuals within the food protection community, current or former employees of government agencies, industry, or institutions of higher learning who have expertise in food protection, are encouraged to apply. IFPTI recruits food protection professionals from varying content areas including but not limited to: unprocessed, manufactured, retail food, feed, food safety programs, food transportation, GAPs, GMPs, imports, food defense, dairy, produce, epidemiology, shellfish, meat, egg, or any other related areas of food safety.

To date approximately 100 instructor candidates have applied through a web-based application. Candidates indicated the existing courses they have an interest in teaching, with an emphasis on FDA core series courses. An instructor development process has been identified to ensure that successful candidates who complete the process meet a high degree of quality and fit for a given course. This process includes the following steps:

- a. Application: Submit a New Instructor Application including references and referrals to become an instructor candidate.
- b. Selection: The IFPTI review committee evaluates new instructor applications and makes selections based on identified priority courses and experience.
- c. Training: Selected instructor candidates must attend the Instructor Development Workshop.
- d. Teaching Experience: After successful completion of the Instructor Development Workshop, the instructor candidate must fulfill three class experiences:
 - i. Attend a course specific instructor training (CSIT) or audit the course the candidate intends to teach (participate as a student).
 - ii. Teaching Experience 1 - deliver 1-2 course modules.
 - iii. Teaching Experience 2 - participate as an instructor.

- e. **Qualified Instructor:** Before an instructor candidate becomes a qualified instructor, the IFPTI selection committee reviews all course evaluations from the lead instructor, students, and an IFPTI-contracted evaluator. Remediation may be required based upon these or future evaluations. The qualified instructor will receive an instructor certificate upon successful completion.
- f. **Instructor Assignment:** Qualified instructors will be assigned to deliver courses based on priority needs.
- g. **Continual Quality Assessment:** To keep current, qualified instructors must attend the Annual Instructor Meeting at least once every three years, where instructors are updated on the FDA vision for the training system for the IFSS and IFPTI processes, procedures, policies, course delivery methods, instructional methodology, and content areas. All qualified instructors must be re-qualified for each course they teach every three years.
- h. **Instructors will be evaluated on a continual basis through:**
 - i. Student evaluations (each delivery)
 - ii. Lead instructor evaluations (each delivery)
 - iii. IFPTI-contracted evaluator (annually)

7. Instructor Management: IFPTI maintains a directory of instructor candidates by collecting and recording profile information within the LMS until all steps of the instructor development process to become a “qualified instructor” are met. The information is categorized based on the instructor candidate’s experience, professional track (unprocessed, manufactured, and retail), content area (e.g., Feed, Food Safety Programs, GMPs, HACCP, Food Sanitation, Food Transportation, Law, Low Acid Canned Foods, etc.), and course preferences. Instructor candidates are sorted based on experience and instructional preference within the LMS, allowing for real-time access to a list of potential instructor candidates for any course. Once instructor candidates become “qualified instructors” their information is transferred into the data management system (DMS) for assignment to specific courses and course offerings.

8. Course Delivery: The IFPTI delivery team is responsible for the management of all aspects of face-to-face course delivery. Needs assessments are conducted to determine specific training needs using on-line survey tools (e.g., Doodle and Survey Monkey). The delivery team surveys and solicits information from food protection officials, agencies, associations, and industry representatives. If survey analysis reveals a training gap, the matter will be referred to IFPTI curriculum specialists for potential new course development. However, if an existing course that fills the gap is identified, the course owner will be contacted to determine course availability and the potential for adaptation to IACET/ANSI standards.

Dates and locations for delivery of in-person courses are predicated on cost effectiveness and geographical efficiency. Course cost estimates are evaluated and approved by the IFPTI Executive Director and the Director of Curriculum Development and Delivery. Upon approval of funding, qualified instructors are nominated by the Instructor Development Coordinator based on knowledge sets and availability using the LMS and the DMS.

A course announcement is prepared, added to the official training schedule, and posted on the IFPTI website. Included in the announcement are details of the course, prerequisites, location, audience, cost (if any), and registration method. The announcement is linked directly to the LMS for secure on-line participant registration.

Course materials are prepared including instructor and participant manuals and other related resource materials and an equipment inventory is performed. Any damaged or missing equipment or training supplies are replaced. If the course is to be delivered off-site, all materials are packed and prepared for shipment to the training facility for arrival as determined by the lead course instructor. Arrangements are secured for required audio/video equipment, as specified by the instructors. Immediately prior to the delivery, welcome packets, name-tags, name-tents, and sign-in sheets are assembled for shipment to the facility. On-line course evaluations and certificates, securely available via the LMS, are verified for accessibility.

On-site coordination is the responsibility of the delivery team or the lead instructor (off-site). If the course is offered off-site all materials and equipment are inventoried to ensure availability for the next delivery.

9. **Training Network Registrar Function:** Establishment of secure career-spanning professional development registration and training records center (hub).

IFPTI has established resources and systems essential to provide registrar functions such as secure registration, training profile information updating, attendance, evaluations, and registry of qualified instructors. Systems and collaborations include establishment of web-based LMS and DMS, and CoreSHIELD (a common organization registry environment that allows for secure real-time sharing of contact data and integrity verification among member organization databases).

- i. **Learning Management System:** IFPTI uses of a robust LMS. A contracted system administrator is working with the IFPTI curriculum delivery staff to develop the LMS system to IFPTI specifications. Once completed, IFPTI LMS online training website will host IFPTI course offerings online, as well as materials,

- discussion boards, and assessments for instructor-led courses. The LMS is also being developed with the intent to track IFPTI instructor candidates' progression through the development process.
- ii. **Data Management System (DMS):** IFPTI has an online data management system that tracks and schedules instructor assignments, accepts instructor time and travel reports, and manages instructor as well as course development.
 - iii. **CoreSHIELD:** In October 2010, IFPTI was approached by the Department of Homeland Security (DHS) to participate in the project to link systems within the Food and Agriculture Sector. DHS has developed a common organizational registry environment (CORE) information-sharing framework called CoreSHIELD that will allow data to be entered once in a linked system but used by other systems within the secure network. The CoreSHIELD platform employs standards and tools that enable partner organizations to communicate, coordinate, collaborate, educate, and train within a framework that facilitates targeted, real-time knowledge of the people, organizations, resources, and capabilities that need to be accessed. At this point, IFPTI is contracting with programmers to ensure the LMS contains linked fields to be able to communicate with CoreSHIELD Food and Agriculture directories such as those contained in FoodSHIELD, FERN, and the Homeland Security Information Network.

10. Job Task Analysis (JTA) Alignment: Alignment of new and existing food safety training courses with JTA outcomes.

IFPTI has collaborated with a curriculum team (a representative group of state and local food protection professionals and university academicians) to design a competency-based, career-spanning, professional development curriculum that encompasses and organizes existing professional development into efficient, effective, standards-driven learning paths. IFPTI is using a curriculum design process known as backmapping, which is defined by the U.S. Department of Education as a tool developers can use to plan results-based professional development.

The backmapping process is focused on initially determining desired outcomes of training or a training program and designing training or a training system to achieve those outcomes. One of the identified tasks is to determine how to use courses that already exist in the curriculum as well as to develop courses to address unmet needs.

IFPTI initiated the backmapping process by convening a curriculum committee (a subgroup of the IFPTI advisory council) to identify and articulate terminal learning objectives for each of the four professional

levels (entry, journey, technical, and leadership) and across four performance dimensions (technical, programmatic, communication, and management/leadership). These terminal learning objectives represent the knowledge, skills, and abilities that federal, state, local, territorial, and tribal government food protection professionals should possess after completing training associated with each professional level.

The curriculum team has identified and defined content areas and competencies for each professional level, track, and content area within the curriculum framework. The curriculum team has also identified professional level-spanning content areas, which are content areas that contain training that all food protection professionals should have regardless of their professional track.

An existing set of competencies was updated, validated, and mapped into the curriculum framework by the curriculum team and a survey of state and local government food protection community members. The curriculum team will articulate the meaning of each competency identified within the content areas, providing metrics for professional development course learning objectives.

IFPTI will map and sequence an inventory of existing food safety training, which has been collaboratively compiled, onto the IFPTI curriculum framework in order to identify and categorize the training by professional level, track, and content area. This process will: 1) help determine learning paths for food protection professionals; 2) allow a gap analysis of existing training opportunities to be performed, resulting in course development prioritization to address unmet needs; 3) identify existing courses that meet the IACET/ANSI standards; 4) encourage course owners to update courses to meet IACET/ANSI standards; and 5) help determine course delivery modalities (online, on-site, blended-learning, etc.).

Once the FDA JTA process has concluded, the IFPTI curriculum team, or curriculum team subgroups, will begin backmapping the identified job tasks to existing courses or course modules and realign the modules as appropriate. A gap analysis will be performed to compare existing training to the JTA analysis outcomes. IFPTI will create, or work with other organizations to create, new courses or course modules to address knowledge, skills, and abilities identified through the JTA process not currently addressed in existing courses.

11. Evaluation Logic Model: Application of an evaluation logic model to guide the outcomes-based development and implementation of the IFSS curriculum.

To assist the evaluation process, IFPTI has developed a logic model for programming learning activities that will greatly impact the overall evaluation process. This logic model was developed collaboratively in an inclusive, collegial process by all stakeholders (e.g., program staff, participants, and external evaluator), which produced a tool to refine learning concepts and the training implementation plans.

To serve a variety of needs, IFPTI focuses on three components of curriculum development and delivery that are incorporated into this logic model: (1) IFPTI-developed courses; (2) sponsorship of IFPTI-approved courses; and (3) providing ANSI-based IFPTI certificates that consist of bundled courses. All three training components are designed to provide scientifically-based career-spanning food protection training for international, federal, state, local, territorial, and tribal food protection professionals to ensure competency and equivalency in meeting established U.S. federal food safety standards.

Thinking about a program evaluation in logic model terms prompts the clarity and specificity generally desired by funding agencies and the scientific community. The IFPTI evaluation process has adopted a simple logic model that produces: (1) an inventory of measurement tools and instruments that IFPTI has developed to operate programming activities; (2) a strong case for how and why these specific activities will produce the desired results; and (3) an ongoing method for program management and assessment.

The actual classification of the logic model type used by IFPTI is structured from an outcomes-based activities approach model that pays the most attention to the specifics of the implementation process. The IFPTI logic model tracks the desired results, which consist of inputs, outputs, and outcomes/impacts. Inputs are what we invest (e.g., staff, equipment, time, technology), outputs are what we do and who we reach, while outcomes measure the short-, medium-, and long-term results. A logic model of this type links the various planned activities together in a manner that maps the process of program implementation. These models describe what a program intends to do and as such are most useful for the purposes of program monitoring and management. IFPTI conducts monthly audits of this model to ensure that continuous modifications and input from project staff for on-going management and program improvement are in evidence.

12. Food and Agriculture Protection Training Consortium (FAPTC). IFPTI participates in FAPTC, which is comprised of eight university-based training centers focused on developing and delivering food protection training primarily to U.S. government food protection professionals at the federal, state, local, territorial, and tribal levels along with others responsible for the safety of the U.S. food supply such as industry, third- party auditors, and regulatory officials in other countries. Member training centers have unique expertise that contributes to the strength of the Consortium. FAPTC provides sustainable, standardized, current, peer-reviewed, on-demand training both domestically and internationally essential for the coordinated prevention and response to food safety incidents impacting the US food supply and citizens. FAPTC members include:

- **Center for Agriculture and Food Security and Preparedness (CAFSP)** at the University of Tennessee
- **Center for Food Security and Public Health (CFSPH)** at Iowa State University
- **Institute for Food Laws and Regulations (IFLR)** at Michigan State University
- **International Food Protection Training Institute (IFPTI)** in Battle Creek, Michigan
- **National Center for Biomedical Research and Training (NCBRT)** at Louisiana State University
- **National Center for Medical Readiness (NCMR)** at Wright State University
- **National Disaster Preparedness Training Center (NDPTC)** at the University of Hawaii
- **National Institute for Food Safety and Security Training (NIFSS)** at Mississippi State University
- **Western Institute for Food Safety and Security (WIFSS)** at the University of California, Davis.

13. Training Research Council: To address long-term outcomes indicated in the logic model, IFPTI formed a national workgroup to serve as a Research Council linking to FDA/CDC national performance metrics efforts. A meeting was held with representatives from CDC, FDA, USDA, DHS, NIH, and others to develop a national impact model, or models, for determining the levels of attribution of a training system for the IFSS in reducing the prevalence of foodborne illness in the United States. The workgroup focused on a key question: What are the metrics to measure the public health impact of a fully-integrated food safety training system? The workgroup agreed that: (1) a rigorous model is needed that will allow collection of information to determine if standards-based training makes a “difference”; (2) training should be linked to probable outcome measures that focus on prevention instead of a reduction in reported foodborne illnesses; and (3) a model should be considered that accounts for quality measures at each step in the food chain to determine knowledge, attitude,

and practice. Communications access for Research Council members was established on DHS CoreSHIELD to share documents and exchange information and updates. The Council agreed to co-author a white paper series: Paper One: Establish “why” a model is needed to determine the effectiveness of an integrated national food protection training system, Paper Two: Propose New Modeling Concepts, and Paper Three: Pilot-Test the Model.

Summary:

To improve skills and increase competencies, the training process demands a systematic, measurable approach. This aids in driving out variance that reduces performance. With an innovative and comprehensive training curriculum and network, IFPTI is the driving force for training in the Integrated Food Safety System. Vetting existing courses and courses in-development to ANSI/IACET quality standards ensures that the nation’s training system meets the quality standards that make training not only acceptable – but exceptional. IFPTI’s instructors come from strong food protection backgrounds, are evaluated regularly and managed directly through IFPTI to establish consistent training across the nation. IFPTI provides a complete training experience that ensures food protection officials, their management, and ultimately the public are confident in the safety of the nation’s food supply.

References:

1. ADDIE instructional design model, http://en.wikipedia.org/wiki/ADDIE_Model
2. Bloom’s Taxonomy, http://en.wikipedia.org/wiki/Bloom%27s_Taxonomy
3. Taylor, M. R., & David, S. D. (2009). *Stronger partnerships for safer food: an agenda for strengthening state and local roles in the nation’s food safety system*. Informally published manuscript, School of Public Health & Services, The George Washington University, Washington, DC, United States of America. Retrieved from <http://www.rwjf.org/files/research/20090417foodsafetyfinalreport.pdf>
4. Food Safety Modernization Act (FSMA), <http://www.fda.gov/food/foodsafety/fsma/default.htm>
5. Kirkpatrick Partners, Kirkpatrick Four Levels Training Evaluation Model, <http://www.kirkpatrickpartners.com/>
6. National Academies Institute of Medicine, (<http://www.iom.edu/About-IOM.aspx>)
7. U.S. Preventive Services Task Force (USPSTF), <http://www.ahrq.gov/clinic/epcix.htm>

Don't Be Haunted By Your Words!

By Nancy Singer and Joseph Pickett

In this article, Ms. Singer and Mr. Pickett offer advice to both government and industry officials on writing clear and concise reports that won't come back to haunt them in the future.

How to Avoid Mistakes in Documents That Destroy Your Credibility and Lead to Legal Trouble

If you think about it, an electronic document is like a diamond. It is very precious, and it lasts forever.

This is especially true in the field of food and health care products. These products are necessities. The people and entities regulating and manufacturing food, drugs and medical devices are highly visible. That visibility is often a plus, but when things go wrong, it can be a minus.

For FDA-ers, you and your documents are under the intense scrutiny of:

- Defense lawyers.
- Office of the Inspector General (OIG).
- Congress.
- Trade associations.
- The media.

Food, pharmaceutical and device firms, you too are under intense scrutiny. The groups that are closely watching you and your writings include:

- The competition.
- Federal prosecutors.
- State prosecutors.
- Plaintiffs' lawyers.
- The media.

Basically, if food or health care products cause harm, the public will blame the product manufacturers and the government—whose job it is to oversee the manufacturing of these products.

So, it is vital to use care when you write emails, reports, and other documents. The consequences of carelessness may not come immediately. But, six years later, during an oversight hearing or in a trial, you could have members of Congress, prosecutors, or the media saying, "Can you *believe* they wrote that?"

For FDA – Lack of Specificity or Evidence in EIR Statements

The *Investigations Operations Manual* (IOM) is the primary source regarding FDA's policy and procedures for field investigators and inspectors. The foreword to the IOM states: "...Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations."

Section 5.10.4 of the IOM says that the narrative report in the Establishment Inspection Report (EIR): "...should be factual, objective, and free of unsupported conclusions. Be concise and descriptive while covering the necessary aspects of the inspection." "

Sounds simple, right?

However, when we reviewed several EIRs, we found statements such as:

Example 1:

"The firm calibrates all of its manufacturing equipment every six months."

This is problematic. Why? First of all, it is vague. But there is a deeper problem. In essence, the investigator has just *endorsed* an unsubstantiated claim of the company. If that company's devices don't work because the equipment manufacturing the device was not properly calibrated, the investigator could have some unpleasant questions to answer.

Here is a better way to convey the same information:

"I reviewed the firm's SOP, which states that the Director of Calibration will calibrate all of the manufacturing equipment every six months. (See Exhibit 1). I reviewed the firm's calibration documentation for the calendar year 2010, and the records reflect that all of the equipment identified in the SOP has been calibrated according to the schedule."

This statement provides clear, concise facts about the SOP. It also makes clear that the investigator verified the company's *records* rather than the company's *actions*.

Example 2:

Another EIR example states: *"The production rooms are cleaned daily."*

A member of Congress would have a lot of fun with this one. Imagine yourself on the receiving end of this question: "If the production rooms are cleaned daily, Mr. Investigator, how can you explain the existence of rodents in the production facility?" Once again, the investigator is setting himself or herself up as the defender of the company's actions.

Here is a better and more accurate way to state this: *“The SOP on sanitation states that the production rooms are cleaned daily.”*

Example 3:

A third vague example from an EIR states: *“The firm uses Yost Pest Control Services, and the firm has not had problems with pests.”*

How nice of you to take the company’s side, Ms. Investigator!

Let’s try that again: *“I reviewed the firm’s pest control reports from Yost Pest Control Services for 2010, which are attached in Exhibit 1. Of the ten reports reviewed, I did not see any reports of rodent activity.”*

For FDA – Know When to Use Active and Passive Voice.

Section 5.10.4 of the IOM on Narrative Report elements states: “Generally, [EIRs]...should be written in the first person using the active voice.”

The FDA Intranet states “Readers prefer active voice sentences, and we should try to use the active voice in most of our business writing... Active voice identifies the action and who is performing it. Unfortunately, much of government writing is in the passive voice....[it] becomes a habit; one we should all work to change.”

To eliminate the passive voice, EIR statements should include answers to the following:

- Who?
- What?
- Where?
- When?
- Why?
- How?

Challenge the significance of each observation by asking, “So what?”

In passive voice, the subject is acted upon. Statements usually are wordy, contain the verb “to be,” and can hide the actor. We want the document to clearly identify the actor. There should be no confusion down the road as to who did what.

Example 1:

In passive voice, the subject is acted upon, and the actor is indistinct.

Passive: “Six records were reviewed and discrepancies were found in each record.”

In active voice, the subject performs the action.

Active: "I reviewed six records and found discrepancies in each record."

Example 2:

Passive: "The Form FDA 483 was annotated by the firm."

Not good. This statement does not answer who, what, or when. The FDA wants to know the facts if something should happen at the firm.

Active: "At the end of the inspection, the firm's Vice President of Quality Assurance, Joe Yakes, annotated each of the items on the Form FDA 483."

Result: If the firm does not follow up on the corrective items, the FDA knows whom to contact.

Example 3:

Passive: "A list of all batches of SAP drugs manufactured since the last inspection was provided."

Active: "At my request, Mr. Bates provided a list of all batches of SAP drugs manufactured from January 2010 through June 2010, which is attached as Exhibit 4."

However, sometimes the passive voice is acceptable, such as when the actor is:

- Unknown: The office was built in 2006.
- Unimportant: The Toal Company's response to the Form FDA 483 was mailed on June 10, 2010.
- Better left unsaid (tact): Your form was written incorrectly.

Here are some other examples of when passive voice is acceptable.

"The previous inspection was classified as VAI."

"No Form FDA 483 was issued."

"The inspection of this Class II device manufacturer was conducted on Nov. 23, 2010."

For Industry – Problems with Passive Voice

To create accurate historical records, industry officials should use the active voice in official documents. Think about trying to reconstruct an incident five years later when a problem arises. By that time, many of the employees who were involved may have left the firm. The documents should state who did what and when they did it.

Section 5.3.6.2 of the IOM states that in order to establish relationships between violative conditions and responsible individuals, the following types of information would be useful:

- What orders were issued? (When, by whom, to whom, and on whose authority and instructions)?
- What follow-up was done to see if orders were carried out (when, by whom, on whose authority and instructions)?
- Who decided corrections were or were not complete and satisfactory?"

Let's apply this to typical corrective and preventive action (CAPA) documentation. The company should state:

- What has happened.
- Why it happened.
- What specific people did about it.
- Why the solutions were effective.
- How the company made sure it would not happen again.

However, the company often uses passive voice in the CAPA report to tell what happened without revealing the responsible parties. Those documents contain no blame, no accountability, and little useful information.

Examples:

"Complaints were received."

"The investigation took place."

"The corrective action was taken."

These vague statements can result in the reader of the document (perhaps an FDA-er or an attorney) not understanding the root cause of the failure, as well as the compliance story.

Again, we need to make sure that future readers can easily understand the accurate story if all those involved in the company incident are gone.

For Industry – Avoid Sloppy Writing.

Let's also look at the industry side. Company employees are often guilty of other types of poor writing that can cause trouble.

Example 1:

This is an example of a statement from an industry document:

"The purpose of this study was to ensure that the coating material #234 will not affect the leak and tear resistance of the latex gloves."

The problem here is that the company employee has injected bias into the statement. The employee should rewrite this to be completely neutral:

“The purpose of the study was to determine whether or not the coating material #234 will affect the leak and tear resistance of the latex gloves.”

Example 2:

“The raw data can be found in Appendix 1. The official data for this study can be found in the mechanical test report.”

What is the difference between raw data and official data? Why not just say “data”?

Example 3:

“This report tested the accuracy of the glucose monitor readings.”

This statement, if read literally, does not make sense. Reports don’t test the accuracy of anything. Reports give readers the findings.

“This report includes the results from testing the accuracy of the glucose monitor readings.”

Conclusion

The federal government has been trying for years to encourage the use of plain, clear language in government documents. In 1998, President Clinton directed agencies to write all documents in concise language. The Office of Management and Budget also formed a group called the Plain Language Action and Information Network (www.PlainLanguage.gov). Vice President Gore even created the “No Gobbledygook” award, which the FDA won on four occasions!

The government wants all of us to use clear language, so that we can keep food and healthcare products safe and reliable. By following these tips, both the FDA and industry can produce clearer and more concise documents in the future.

Coordination of State Drug and Pharmacy Laws

Robert P. Fischelis, Secretary and Chief Chemist

Board of Pharmacy of the State of New Jersey

(reprint from AFDO Journal -- Volume II, Issue No. 1, January 1938)

There are many disadvantages to the present divided governmental control of the production and distribution of drugs and medicines within state boundaries. These disadvantages affect not only the governmental agencies which are charged with administration of existing laws and regulations but also the public in whose interest the laws and regulations are presumably enacted. They also affect producers and distributors of drugs and medicines. It seems almost superfluous, therefore, to argue in favor of co-ordination of laws and regulations which affect so vital a matter, from the standpoint of the public health and welfare, as the production and distribution of drug, and medicines. However it is not an easy matter to coordinate statutes enacted by successive legislatures which have been subjected to a variety of pressure groups functioning in support of the outstanding issues of the times during which the respective legislatures were in existence.

If we could make over our pharmacy and drug laws today in every state without regard to existing enforcement agencies and precedents, we would undoubtedly be able to frame laws which would give us a maximum of protection for the public, a minimum of inconvenience for the producer and distributor, and sufficient authority to enable the enforcement agency to serve efficiently and effectively in the public interest. Unfortunately it is not possible under present conditions to bring about a complete revision of the laws governing the practice of pharmacy and the drug industry 'without much opposition. Some opposition would come from those adversely affected by any change from existing laws. Some opposition would come from law enforcement agencies whose activities would have to be merged or abolished altogether, and considerable opposition would come from those who are opposed to any kind of governmental control for any phase of the drug industry.

With this situation in mind, it is not surprising to find legislators unwilling to come to grips with a problem that needs profound study and early attention. It is so much easier to offer an amendment to some existing law in an endeavor to correct a situation which has attracted public attention because of its very rankness, than to perform a major operation which would repeal ineffective statutes and substitute for them strong laws based upon knowledge of the

abuses in the drug industry and intended to co-ordinate regulatory measures so as to correct the abuses at their source.

Let us consider the type of public health problem which requires co-ordination of state drug and pharmacy laws. In a city of 50,000 inhabitants a registered pharmacist selects as the site for his new drug store a corner which is just two blocks removed from a well conducted prescription pharmacy. He has looked the situation over and he must know very well that another drug store is entirely unnecessary in this locality but there is no law to stop him from establishing a drug business any place he cares to. Since the pharmaceutical requirements of the neighborhood cannot support two drug stores he decides that the best method of establishing himself in this locality is to cater to the soda fountain and lunch business. Therefore, he equips the full length of one side of the store with tables, at which the products of the soda fountain and luncheonette can be served. On the opposite side of the store he locates a soda fountain occupying half the full length of the store. Next to this he places a cigar counter occupying another quarter of the length, and then he has a short space to be used as a wrapping counter and a place for the cash register. There is the usual array of display cases and drawers for stocking the many sundries customarily associated with a retail drug stock. Six feet of space remain in which to fit a prescription department. The owner, mind you, is a registered pharmacist. The State Board of Pharmacy has given him a license to practice pharmacy upon completion of the requirements for registration and passing the licensing examination. In the eyes of the law he is qualified to dispense drugs, medicines and poisons and to compound prescriptions. Presumably, he is acquainted with the dangers involved in dispensing food in the close proximity of a drug and prescription laboratory.

About 60% of the drugs he will sell are packaged remedies, commonly identified as patent or proprietary medicines. He has no worry about these because they are supplied in packaged form and he is required to assume no responsibility whatever in connection with them because the laws provide that such preparations shall be completely exempted from all provisions of the state pharmacy act. Furthermore, some courts have held that as long as these products are of secret composition and purveyed to the public in labeled packages, the registered pharmacist is not expected to know any more about them than the most ignorant layman. As a business man he is more concerned about the status of such packaged remedies under the fair trade laws than under the pharmacy or drug laws, for they are nationally advertised and subject to public demand regardless of quality or efficacy and they are frequently made footballs of cut-price competition. About 25% of his business in drugs will be in so-called home remedies, which are the conventional Pharmacopoeial and National Formulary preparations. These he could put up himself if he had the space and inclination to do so, but for various reasons he follows the example of nine out of ten of the craft and purchases them from pharmaceutical manufacturers.

If this pharmacist should obtain a license from the Board of Pharmacy to conduct a prescription pharmacy, another 15% of his drug business may consist of prescription work. Probably 50%, or more of the prescriptions will call for proprietary preparations, sometimes referred to as ethical proprietaries, because at their beginning they are introduced through the medical profession. Actually, of course, the so-called ethical proprietary medicine of today is the publicly advertised patent medicine of tomorrow. The balance of his prescription work may require some extemporaneous compounding.

All of these activities are carried on in the one room under ever varying conditions, depending upon weather, the appetite for food of his clientele, the character and ethical background of the proprietor and the characteristics of the consumers in the particular trading area.

The food department of this particular establishment must, of course, conform to state and municipal health regulations. The compliance with these regulations will depend largely upon the degree of efficiency with which existing laws and regulations are enforced. There will undoubtedly be some state and local inspections. The Department of Weights and Measures, state and local, will inspect the weighing and measuring devices in both food and drug departments of this store. If there is an efficient Board of Pharmacy in the state and a permit is required to operate a pharmacy, the permit will be granted only after certain requirements have been met. In some cases the requirement is merely the payment of an annual license fee. In other states the license fee is accepted only after it has been shown that minimum standards of equipment have been met. In such cases there will be inspection of the drug department to determine that necessary apparatus, adequate space and other facilities have been provided to dispense drugs and medicines and to compound prescriptions.

Already we have enumerated at least four agencies operating under at least four different state laws which have some control over some part of this establishment. Add to these the Federal and State Alcohol Administrations, which exercise control over the use and dispensing of alcohol, the Federal and State Narcotic Departments, exercising control over the purchase and dispensing of narcotics, and other agencies which have control over some phases of drug store operation, and you begin to see a picture of the need for co-ordinated effort. Not one of the agencies enumerated has complete control over the activities of a so-called drug store. Yet the drug store is the outlet for approximately 85% of the drugs and medicines consumed by the general public.

Across the street from this newly established drug store another individual with no background of training in the drug industry, but with sufficient capital, opens a store which almost duplicates the drug store we have just described. Again one side of the establishment is devoted to tables for serving soda fountain products and luncheons. The other side is half soda fountain, one-quarter cigar case and the six feet which are devoted to the prescription department across the street are here devoted to patent medicines. Virtually the same patent and proprietary medicines sold in the drug store across the street may be sold in this establishment without hindrance and without the services of a registered pharmacist and remember that accounts for 60% of the total business in drugs and practically 100% of the business in nationally advertised medicines. The Health Department is, of course, interested in the soda fountain and in the food supplied. The Weights and Measures Department has no interest in the establishment because there is no bulk or loose dispensing. The Federal and State Alcohol Departments have no interest in the place for similar reasons. The Federal and State Narcotic Bureaus pass it by because no narcotics are bought or sold. The Board of Pharmacy has no authority to license or withhold license from this establishment as long as the sales of drugs are confined to patent or proprietary medicines with the possible exception of those containing poisons, hypnotics, or narcotics. However, these exceptions do not hold good for all states.

The type of store here described, is of course, not the kind that is usually referred to as a pharmacy. However, with the exception of the prescription department and the stock of poisons and official drugs sold as home remedies, it carries the same commodities although it is subject to none of the legal supervision exercised in the case of the drug store. Here we have another example of elaborate supervision and regulation of services and establishments conducted by those especially qualified by law to render such services and practically no supervision over those who are not required to demonstrate any competence whatever in this field of activity.

Enough has been said to indicate the need for a type of supervision over establishments dealing in drugs and medicines, which will take into consideration their services to the community as a whole, and not confine itself to regulation and supervision of individual activities coming under the separate jurisdiction of a variety of law enforcement agencies.

It goes without saying that general supervision over retail drug stores and the activities carried on in the establishments of producers and distributors of medicines should be in charge of agencies having special experience in this field.

The licensing of manufacturers of drugs and medicines with the enforcement of special requirements as to personnel, equipment, and quality of products, seems to be a modern necessity. Supervision of such establishments is peculiarly a state function, because all drugs and medicines produced within the United States are made within the boundaries of some State or Territory or the District of Columbia. Why should the entire burden of supervision of such establishments be vested in the Federal government which cannot exercise authority in any event until their products reach interstate commerce? Is it not too late in many cases to begin supervisory activity when the products of a manufacturer have left his laboratories and crossed state boundaries? So much harm could be prevented if the same strict supervision now exercised over retail drug stores within state boundaries by Boards of Pharmacy in many states could be extended to the manufacturing and warehousing establishments concerned with drugs and medicines. It is useless to provide for such supervision by law however, unless the enforcement is placed in the hands of agencies and individuals qualified by training and experience to deal with the problems arising from such supervision.

State supervision backed by a Federal licensing system which would require manufacturers to demonstrate the quality and safety of their products, would insure the public against recurrence of such ghastly disasters as the Sulfanilamide "Elixir" tragedy through which we are now passing.

At the recent annual meeting of the American Pharmaceutical Association the Committee on the Modernization of Pharmacy Laws indicated that Boards of Pharmacy as selected on a political basis in many States today, are not competent to function in all the fields of activity usually assigned to them under the Pharmacy laws. To remedy this situation it was proposed to establish State departments of pharmacy with administrative boards consisting of representatives of the profession and the industry as well as the public. How political considerations were to be avoided in the naming of such Boards was not indicated. It is doubtful whether a mixed administrative Board would present any advantages over the present type of Pharmacy Board unless there is provision for a strong administrator with broad powers such as are now granted to highway commissioners, motor vehicle commissioners and health commissioners appointed for their specific training and abilities and classified as career men in the highest sense of that term.

We all know of health departments consisting of political appointees who in return select health officers with little background or qualification for the job. Recent events have again proven that the regulation of production and distribution of drugs and medicines must be placed in safer hands if we are to avoid tragic results.

Much more important than the selection of a composite Board representing industry and the public is a recognition of the potential and insidious dangers connected with the production and distribution of drugs and medicines, followed by a real effort to place their regulations in the hands of someone with sufficient knowledge to insist on an interpretation of existing laws in the interest of the consumer and with sufficient courage to point out the various subterfuges which have been resorted to in order to secure legislation and legal interpretations favoring unrestricted distribution of drugs of questionable value under questionable conditions.

State pharmacy and drug laws should be coordinated with respect to definitions of terms. There should be a greater tendency on the part of all enforcement agencies to lean toward strict construction rather than loose construction of important terms, wherever there is imminent danger to health. Nothing is more detrimental to efficient enforcement than to find one governmental agency practically nullifying the work of another by different interpretations of laws or regulations which overlap. Much credit must be given the Food and Drug Administration for the efficient work of its Bureau of Cooperation. There is much better coordination of Federal and State enforcement of food and drug laws than is frequently found in connection with pharmacy and drug laws in some of our States.

It would seem to be highly desirable for some group to initiate occasional State conferences between all enforcement agencies which touch upon the production and distribution of drugs and medicines. The district meetings of health and food and drug officers partially cover the purpose but they rarely consider topics relating to drugs. Furthermore they do not bring together all the agencies in a single State and that seems essential to mutual understanding of State problems. The presence of a federal official at such conferences would be highly desirable. Such coordinating conferences will become particularly necessary after new federal food and drug legislation is enacted in order to avoid disjointed state legislation and overlapping enforcement.

Among topics that could be discussed with profit by such groups are the following:

1. How far can advertising that is palpably false and misleading, with respect to drugs, be controlled under State advertising laws if the co-operation of prosecuting authorities is forthcoming? So far there seems to have been no attempt made to place this problem before Grand Juries. Even the attempt might be helpful in controlling this growing menace.

2. Under what conditions would it be advisable for all State agencies to take joint or individual action against the same individual or corporation in order to correct a glaring public evil?
3. Would coordinated inspections by representatives of various pharmacy and drug law enforcement agencies, State and local, be justified in cases where a particularly harmful situation exists?
4. Would it not be in the public interest for all agencies concerned with laws affecting any phase of pharmacy or drug regulation to lean toward the general policy of confining manufacture and distribution of all types of drugs and medicines to licensed pharmacists and pharmacies?
5. Would it not be in the public interest for these same agencies to work toward the elimination of the unscientific, arbitrary, and unsound classification of remedies into drugs and medicines and patent or proprietary medicines as written into our pharmacy laws years ago for no other purpose than to free the patent and proprietary medicines from all restrictions as to production and distribution?

Where Are We Headed -- And For What Are We Striving In Regulatory Control Activities

W. C. Geagley, State Analyst

Department of Agriculture, Lansing, Michigan

(reprint from AFDO Journal -- Volume II, Issue No. 2, April 1938)

The subject to which I desire to direct your attention is the multiplicity of laws, regulations, orders and rulings emanating from every unit of government...To be sure, when evils begin, or if abuses prevail, they should be curtailed and corrected. And, quite naturally, governmental agencies have been shown to be the only agencies that can adequately cope with conditions in society and industry and, bring, about needed correction...With the continual and ever-changing personnel--in many instances consisting of uninformed, inexperienced, unqualified administrative and executive people--we have still more and more illogical regulations, edicts and orders that may not be to the best interests of either the public or the industry...Everyone has witnessed, or experienced, laws and regulations that have not met with the approval either of the industry (as a whole) to be regulated, or the people intended to be served. Cannot this same comparison be made with food laws, for instance, drug laws and many other phases of social and industrial life that are so closely regulated today?

In contrast to what might appear as over-regulation, let me point out another industry of comparatively recent development that has grown each year by tremendous leaps and bounds...It has not been hampered with standards, with formulas, with administrative restrictions or with the yardstick of governmental control...Until today the automobile industry has no equal in efficiency in our modern scheme of life...Quite naturally, then, the question could be asked whether this industry would have developed to the extent that it has, had it been under close supervision. My candid opinion is that this would not be the case.

DISCUSSION BY C. S. LADD, State Food Commissioner and Chemist, North Dakota Regulatory Department, Bismarck, North Dakota.

The conference is considering food and drug laws and allied laws, their enactment and enforcement.

I believe we should be striving to give the greatest possible protection to the public with the laws we have and should be working for the enactment of more adequate laws in the fields now covered and for laws to correct abuses in the case of other products.

According to the program, this afternoon is one intended to be devoted to matters "Regulatory." I do not like the term "Regulatory" in this connection and do not feel that it is properly descriptive. Our work is primarily concerned in the protection of the public, and this should be emphasized. But there is more than protection involved in order for the public to have the protection they want, need, and are entitled to. There are at least three vital phases--involving (1) consumer education (2) consumer information, as well as (3) consumer protection.

In order that the people of all of the states may obtain these things most efficiently there should be uniformity between the laws of the states and between those of the states and the national law. In order to do this the strong laws should not be weakened but rather the best should be retained and efforts made to bring other laws up to that of the most efficient. Too many laws are largely the result of compromise because of influences which have been exerted in legislation by interested parties, because of lobbyists and lawyers representing not the best elements of manufacturers and sellers; but those who have sought to secure the weakest compromise of a law in order that they might still continue the sale of poor or worthless products, fakes, frauds, and discredited drugs or products containing inexpensive ingredients under a fanciful name at exorbitant prices. Usually this compromise is effected only after long delay so that those leaders working for true protection and in a spirit of righteousness and good citizenship are worn down, discouraged, and forced to drop the fight because of the lack of financial support to carry on and the time involved.

Regardless of all of this it is encouraging to note that definite advances can be and have been effected with perseverance.

The biggest handicap in many states to obtain adequate food and drug legislation as well as in the enforcement of the laws enacted, is the short tenure of office and short-sighted political influences. No matter how honest, sincere, and capable, no one can come to familiarize himself with and appreciate the many ramifications of the laws in relation to the innumerable products and situations in a period of from two to four years, and this is about as long as one is appointed by political parties, is permitted to hold his office. And underlings are too often, usually to a large extent, also replaced. We should obtain civil service protection for the latter at once and insist on a non-political enforcing officer.

The worst abuses practiced upon our fellowmen continue to be the sale, under fanciful names or as patent or proprietary products, of practically worthless concoctions or inexpensive drugs at exorbitant prices with promotional methods insinuating an unlimited value for them. We believe in North Dakota that we have taken a definite step toward curbing these practices by amending

the drug provisions of our Food and Drugs Act to include the same provision in respect to drugs as has for many years in North Dakota applied to similar classes of foods. This requirement is that if a drug is not designated by a name recognized in the U. S. P. or N. F., it is misbranded if its label fails to bear the common or usual name of the drug, or if it is composed of two or more ingredients; the name of each active ingredient; and further that if necessary to prevent fraud or deception, or to convey to the purchaser the true nature of the product, the percentage of each ingredient shall in addition be required.

Other amendments to the drug provisions enacted in North Dakota this year included some of the best proposals which have been in the various bills that have been pending in Congress during the past several years. Not perfect but a definite improvement.

Very few states have been sufficiently active in drug work to render adequate protection and I believe each state that has not been doing so should carry on some work in this direction.

DISCUSSION BY P. R. DUNBAR, Ph.D., Assistant Chief, Food and Drug Administration, United States Department of Agriculture, Washington.

Mr. Geagley was good enough to supply me with an advance copy of his paper. I must confess that my first reading of it left me staggering mentally. I concluded, however, that his object was to throw a sort of rhetorical bombshell into the meeting for the purpose of provoking discussion, and from the unanimous way in which during the ensuing discussion his State colleagues have rallied to the defense of more and better food and drug laws, it is evident that he has attained his objective.

I presume that there are few of us who have not, in moments of reverie, pictured an ideal existence, probably somewhere in the South Sea Islands, "where there ain't no ten commandments" and where policemen and big sticks are non-existent. I have no doubt that everyone of you here present could inhabit a paradise of that kind, ungoverned and beyond the control of any law except the Golden Rule, and never need the supervision of a law enforcing agency. Somehow, I am reflecting on the charms of such an existence, it occurs to me that there is a select list of individuals that I should be perfectly happy to assist out of this world--let's call it execution for the good of humanity--if I had no fear of legal penalties. But then it occurs to me that possibly the intended victim might be just a little quicker on the draw than I am, so I conclude that I am not particularly anxious to inhabit a community that is without law. Civilization implies the existence of law--law not to govern the civilized but to control the uncivilized and the bandit class.

But we are talking about food and drug regulatory laws. It is impossible, I think, for anyone who is familiar with the history and application of such laws to deny their essential and beneficent character; and yet we cannot deny that their enforcement as a whole causes annoyance to the governed class and imposes costs on the very elements they are intended to protect. You heard Dr. Ruhland assert that since the turn of the century infant mortality has been reduced 60 per cent by reason of the adoption of strict milk ordinances. Can anyone doubt the beneficent character of these laws regardless of the fact that they undoubtedly impose burdens and worries upon the milk producers? Every civilized country has health quarantine measures of a kind that were not even dreamed of in our father's time, measures which have almost eliminated dangers of nationwide plague infestations that only a generation ago constituted continual menaces, particularly in our southern border ports. These laws imposed burdens upon many, on transportation lines, upon the traveling public, upon business men in general. Does anybody contend that they would wish to dispense with such statutes? No, I do not think we have come to the time when we can dispense with laws intended for the protection of the public health and I am confident that Mr. Geagley did not intend to imply as much.

I was intensely interested in the recital in the President's address this morning of the various epoch-making events in the way of regulatory control activities. I recall very distinctly that in the early days of enforcement of our Federal law, beginning in 1907 and for a period of ten or fifteen years thereafter, offenses of the most flagrant kind were common. It was a comparatively easy matter to discover and eliminate these offenses because of their self-evident character. Many of them were promptly suppressed by the trade itself as soon as they were assured of governmental protection through the imposition of penalties upon competitors who failed to meet the strict requirements of the statute. But it seems to me that after that period of let us say fifteen years, we reached a sort of plateau when for some few years at least we proceeded on a dead level, dealing only with the more or less stereotyped classes of violations, uncovering very little of a sensational character leading us into new fields of regulatory endeavor. I recall at about that time a conversation with a man formerly well known and deeply interested in food and drug regulatory work. He made the assertion to me that he felt that food law enforcement had about reached the limit of its development--that increased forces and increased funds would hardly be necessary in the future but that only a sufficient group of inspectors and chemists need be maintained to see that industry did not revert to abuses previously corrected.

It is interesting to enumerate the regulatory campaigns involving violations of the utmost importance from the public health standpoint which have been inaugurated since that time. I can take time to mention only a few but these are sufficient to demonstrate the fallacy of the conclusion that we had reached the end of our regulatory program. I need only mention the spray residue

problem, the control of botulinus outbreaks, the campaign now under way for improving the quality of dairy products, and the even more recent development involving flour--most of them programs far more vital to the public welfare than most of the campaigns which preceded them in the early days--to justify the conclusion that our work is only beginning. The very latest indication of the ever present character of our regulatory responsibility is shown by the columns of the daily press within the last few days, descriptive of the catastrophe which has followed the distribution of an elixir of sulfanilamide so toxic as to have resulted in perhaps hundreds of deaths. Our subject is "Where are we headed and for what are we striving in regulatory control activities." We should consider first what we are striving for. We are striving for only one thing essentially and that is public protection, the conservation of the public health and the public welfare. It is true that in the course of this effort, incidentally we protect the honest manufacturer against unfair competition of unscrupulous rivals. But that activity is an incidental by-product of the main objective, namely, the protection of the ultimate consumer.

And where are we headed? Our objective must be better and more effective laws, whether they be State or National. I cannot say too much in commendation of the splendid cooperation which has existed between all agencies in the handling of the problems we have had presented to us but we are handicapped by the limitations of a statute that is more than 30 years old. There is no use repeating here the many essential provisions which we must procure if we are to render effective service. I am glad that Commissioner Ladd referred to the need for legal standards. It is gratifying that many states have authority to set up such standards. The lack of such authority in the Federal statute has been undoubtedly the greatest handicap with which we have been faced in applying the terms of the law to adulterated food products. Only last week in El Paso the Government was defeated in a hard-fought case involving the distribution of a badly substandard preserve because of the strictly legalistic attitude adopted by the court which held that the Government had not established a legal standard for that product. We must have legal standards for really effective enforcement and we are undoubtedly headed for such standards. Then, too, there must be a method of control for products which are potent for damage to public health, more effective and more expeditious than the present cumbersome method of awaiting interstate shipment and then determining by objective examination of a sample collected after shipment that the product is dangerous to health. I may cite our experience with crabmeat in which we have had success largely because of the splendid assistance given by many State authorities in cleaning up bad conditions at the source. A type of protection that depends on the hit-or-miss method of sampling at destination as a guaranty against danger from polluted foods is inadequate and obsolete. I do not advocate continuous governmental inspection in all food and drug manufacturing plants. It would be effective but enormously expensive. But I do insist that such inspection, or as an alternate an effective licensing scheme, is

essential in those industries dealing with commodities which may have a damaging effect upon public health if not properly controlled. Under the Meat Inspection Act our meat supply is inspected and adequately policed. Under the sea food amendment canned shrimp is subject to a comparable type of Federal inspection which guarantees that the consumer may buy that product with entire confidence. Is there any reason why other perishable food products of like character should not be subject to comparable supervision? This is what we are headed for and until we reach that objective consumer protection will not be fully assured.

NASDA News Release: 2011 Raw Milk Survey

NEWS RELEASE

FOR IMMEDIATE RELEASE
July 19, 2011

Contact: Bob Ehart
(202) 296-9680

NASDA RELEASES RAW MILK SURVEY

Washington, D.C. – The National Association of State Departments of Agriculture (NASDA) has released updated results from a Raw Milk Survey.

NASDA conducted a Raw Milk Survey, in cooperation with the National Association of Dairy Regulatory Officials (NADRO), to gather current information about the regulation and sale of raw milk in the United States. Raw milk is defined as milk that has not been pasteurized. The Center for Disease Control (CDC) strongly discourages consumption of raw milk as pathogens from raw milk can result in kidney failure, paralysis and fatality, in some cases.

This survey is NASDA's third collection of data since 2004. In 2008, 50 states participated in the survey and 30 states allowed raw milk sales. NASDA's new data reflects no change in the number of states permitting unpasteurized milk sales both on the farm and in retail markets. The 2011 data shows the same 30 states allowing raw milk sales. Likewise, the same 20 states still prohibit the sale of raw milk to consumers. Five states have adopted stricter quality standards to regulate the sale of raw milk since the 2008 survey.

Of the 30 states where raw milk sales are allowed in some form, 13 states restrict legal sales to occur only on the farm where the milk is produced. The survey shows that 12 other states allow the sale of raw milk at retail stores separate from the farm. The remaining five states restrict the availability of raw milk to special markets or have compound regulations.

NASDA represents the commissioners, secretaries, and directors of the state departments of agriculture in all 50 states and four territories. The information for this survey was received from the NADRO members in each state.

-30-



The National Association of State Departments of Agriculture (NASDA)
1156 15th Street, N.W., Suite 1020
Washington, D.C. 20005
202-296-9680 e-mail nasda@nasda.org
<http://www.nasda.org/>
President: Valoria Loveland, Washington State Department of Agriculture

Summary of results:

Of the 50 respondents, 30 states authorize the legal sale of raw milk, in some specified manner, for direct human consumption. The remaining 20 states prohibit the sale of raw milk to consumers. The following data represents the 30 states that allow raw milk sales in some form.

Sales of raw milk restricted to the farm:

- 13 states restrict legal sales to occur only on the farm where the milk is produced (AR, IL, KS, KY, MA, MN, MS, NE, NY, OK, RI, TX, WI)
 - Four of these states (MN, WI, OK, IL) further restrict sales to only incidental occurrences (i.e., occasional; not as regular course of business; no advertising)
 - Kansas allows sales directly to the consumer on the farm with minimal on-farm advertising.
 - Four states (AR, KY, MS, RI) restrict sales to goat milk only, with two states (KY, RI) also requiring a prescription from a physician
 - AR allows 100 gallons of raw, liquid goat milk to be sold from the farm each month.
- 5 states have a coliform standard for milk sold only on-farm (ID, MA, NY, OR, TX)

Sales of raw milk at retail stores separate from farm:

- 12 states allow the sale of raw milk at retail stores separate from the farm (AZ, CA, CT, ID, ME, NH, NM, NV, PA, SC, UT, WA)
 - One of the 12 (UT), requires the store to be owned by the producer, even though it can be located off of the farm.
 - Another state (SC) allows the sale of raw milk both on and off the farm and at farmers' markets if a permit is obtained. Further, farmers must provide retail stores with a warning plaque to be displayed in front of the raw milk.
- Of these 12 states, all 12 have a total coliform standard.
 - 9 states have a coliform standard of $\leq 10/\text{mL}$ (AZ, CA, ME, NH, NV, PA, SC, UT, WA)
 - 1 state has a coliform standard of $\leq 25/\text{mL}$ (ID)
 - 2 states have a coliform standard of $\leq 50/\text{mL}$ (CT, NM)

Sales of raw milk at farmers' markets and states with compound regulations:

- 5 states have unique regulations that do not fit in either of the categories above. (CO, MO, OR, SD, VT)
 - One state (OR) allows on-farm sales of raw cow's milk only from farms with no more than two producing cows, nine producing sheep and/or 9 producing goats; Only goat milk is allowed at retail off farm.
 - Of the five states, one state (CO) prohibits all sales of raw milk; however, raw milk may be legally obtained through "share" operations.
 - Another state (VT), allows raw milk to be sold on the farm and if farmers comply with further standards they are also allowed deliver to retail stores. Raw milk sales are prohibited at farmers' markets and advertising is not restricted.
 - Two states (SD, MO.), allow farmers to deliver to farmers' market but not to stores.
 - Of these five states, 4 have minimum standard requirements (MO, OR, SD, VT)
 - 1 state has a coliform standard of $\leq 10/\text{mL}$ (VT, OR)
 - 1 state has a coliform standard of $\leq 100/\text{mL}$ (MO)
 - 1 state requires the same standards for raw milk as pasteurized milk (SD)

The Sale of Raw Milk is prohibited in 20 States: (AL, AK, DE, FL, GA, HI, IN, IA, LA, MD, MI,

MT, NJ, NC, ND, OH, OK, PA, RI, SC, TN, VA, WA, WI, WY)

1156 15th Street, N.W., Suite 1020

Washington, D.C. 20005

202-296-9690 e-mail nasda@nasda.org

<http://www.nasda.org/>

President Valeria Loveland, Washington State Department of Agriculture



(# # #)

2011 Survey Questions:

1. Is the sale of raw milk for direct human consumption legal in your state?
2. Do your state laws or regulations expressly prohibit animal share raw milk operations?
3. Do your state laws or regulations authorize raw milk sales only on the farm?
4. Are raw milk sales at retail stores or markets, separate from the farm, legal in your state?
5. Does your state have any microbial standards for raw milk sold to the consumer? If yes, please specify.
6. Is sampling for compliance with the above standard(s) conducted at the farm bulk tank, or at the final package/bottle?
7. Are there any county or local government bans on raw milk sales in your state?
8. Approximately how many producers of milk to be sold raw are operating in your state?
9. What has changed regarding the regulation of raw milk since the 2008 survey?



The National Association of State Departments of Agriculture (NASDA)
1156 15th Street, N.W., Suite 1020
Washington, D.C. 20005
202-296-9680 e-mail nasda@nasda.org
<http://www.nasda.org/>
President Valoria Loveland, Washington State Department of Agriculture

Guidelines for Exempt Slaughter and Processing Operations, Revised June 2011

INTRODUCTION

The Association of Food and Drug Officials (AFDO) has developed this guidance for state and local jurisdictions on the regulation of the slaughtering and processing of animals for human food in operations not subject to mandatory inspection under federal laws. Such animals may include amenable species (cattle, swine, sheep, goats, chickens, turkeys, ducks, geese, etc.) being processed under a custom slaughter or other exemption to federally-mandated inspection, and non-amenable game animals and exotic species that are not subject to federally-mandated inspection. AFDO finds that guidance currently available to regulatory officials on commercial practices and regulatory surveillance in this area of food production is sparse and inconsistent.

These guidelines are intended to provide a national standard for the regulation of slaughter and processing operations not subject to mandatory inspection under federal laws. Although the regulatory needs of various states may vary, AFDO encourages uniformity in the application of best practices to similar food production operations in all locations.

Although the inspection requirements of the Federal Meat Inspection Act (21 U.S.C. 601, et. seq.) and the Federal Poultry Products Inspection Act (21 U.S.C. 451, et. seq.) may not apply, the Acts' adulteration, misbranding, and humane handling provisions do apply to exempt operations. Accordingly, these AFDO-recommended best practices reflect and expand upon the minimum USDA requirements for these operations under federal laws.

These Acts require that custom exempt operations:

- Not adulterate or misbrand products;
- Handle livestock humanely;
- Prepare products under sanitary conditions;
- Keep certain records;
- Properly mark, label, and package product; and
- Keep exempt products separate from inspected products.

This document was produced through AFDO in coordination with a task force of experts from the United States Department of Agriculture, Food Safety and Inspection Services (USDA/FSIS) and representatives of state meat or food safety inspection programs.

AFDO wishes to thank the following state representatives from the task force:

Terry Burkhardt, Wisconsin
Larry Decker, New York
Dr. John Fruin, Florida
Dr. Douglas Hepper, California
Dr. Lee Jan, Texas

Dr. Fruin and Larry Decker are from state food safety programs, and Dr. Hepper, Terry Burkhardt, and Dr. Jan are from state meat inspection programs. In addition, technical experts from USDA/FSIS served as advisors. AFDO staff also participated.

The 2011 edition was updated by the AFDO Meat and Poultry Committee, chaired by Stan Stromberg, Oklahoma, in conjunction with members of the National Association of State Meat and Food Inspection Directors, and the AFDO staff, in cooperation with USDA/FSIS.

DEFINITIONS

For the purposes of this guidance document, the following definitions apply:

1. *“Adulterated”* means any carcass or part; any meat or poultry, or meat or poultry product that is unfit for human consumption, as defined in 9 CFR 301.2.
2. *“Air-injection stunning”* means captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle.
3. *“Custom slaughter”* or *“custom processing”* means the slaughter or processing services provided to an individual who already owns the affected food animal, either wholly or in part, and meat from these animals that will be used solely for household consumption, by the owner, members of their household, employees, and non-paying guests.
4. *“Exempt slaughter”* or *“exempt processing”* includes custom slaughter or custom processing, as well as the exempt slaughter and processing activities that are exempt under the Federal Meat Inspection Act and Poultry Products Inspection Act.
5. *“Food animals”* means all the following:
 - *“Domesticated food animals.”* This includes cattle, swine, sheep, goats, rabbits, farm-raised deer, poultry (chickens, ducks, geese, turkeys, guineas, squab), and ratites.

- “*Captive game animals.*” This includes bison, whitetail deer, and other animals of a normally wild type that are produced in captivity for slaughter and consumption.
 - “*Captive game birds.*” This includes farm-raised game birds, such as pheasants, quail, wild turkeys, waterfowl, and exotic birds, which are produced in captivity for slaughter and consumption.
6. “*Individual*” means one, or a single, human being.
 7. “*Individual Exemption*” allows for an individual to slaughter and/or process animals owned wholly by that individual that will be used exclusively in the household of the individual, members of their household, non-paying guests, and employees. The individual exemption does not apply to the slaughter and/or processing of animals owned wholly or in part by another individual.
 8. “*Meat*” means the edible muscle and other edible parts of a *food animal*.
 9. “*Meat establishment*” means an establishment used to slaughter *food animals* for human consumption or to process the *meat* of food animals for human consumption.
 10. “*Mobile custom slaughter*” or “*mobile custom processing*” means custom slaughter or processing services provided at the recipient’s premises (typically a farm), rather than at a *meat establishment*.
 11. “*Non-ambulatory disabled livestock*” means livestock that cannot rise from a recumbent position or that cannot walk.
 12. “*Person*” includes any *individual*, partnership, corporation, limited liability company, association, or other business unit, and any officer, agent, or employee thereof.
 13. “*Sanitary*” means free from dirt, filth and contamination and free from any other substance or organisms which are known to be injurious to human health or which would render the product adulterated.
 14. “*Wild game*” means an animal, the products of which are food that is not classified as a domesticated *food animal captive game animal*, or *captive game bird*. This includes wild deer, elk, antelope, moose, bison, bear, rabbit, squirrel, raccoon, and wild birds such as pheasants, quail, and turkey.

REGISTRATION AND AUTHORITY

1. No person, firm, partnership or corporation not granted inspection pursuant to the Federal Meat Inspection Act or the Federal Poultry Products Inspection Act shall operate any place or establishment where food animals are exempt slaughtered or exempt processed for food unless such person, firm, partnership or corporation is registered or licensed by the state or local regulatory agency. An application for registration or license shall be made upon a form prescribed by the regulatory agency.
2. In performance of their registration and inspection duties, authorized representatives of the regulatory agency shall have access to, and may enter at all reasonable hours, all places where food animals are exempt slaughtered or exempt processed.

CONSTRUCTION

1. Establishment buildings, including their structures, rooms, and compartments, must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or creation of insanitary conditions.
2. Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and must be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.
3. Walls, floors, ceilings, doors, windows and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.
4. Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and creation of insanitary conditions.
5. The exempt slaughter or exempt processing establishment shall maintain well-distributed and sufficient light of good quality.
6. Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.
7. The exempt slaughter or exempt processing establishment shall maintain an efficient drainage and plumbing system for the establishment that prevents adulteration of product, water supplies, and equipment, or the

creation of insanitary conditions. The premises and all drains and gutters shall be properly installed with appropriate traps and vents to convey sewage and liquid waste from the establishment and prevent back-flow conditions and cross-connection between waste water/sewage systems and piping systems that carry potable water. The establishment shall obtain a letter or certificate from the responsible local authority or an accredited third party that the sewer system meets all local environmental standards.

8. The water supply shall be ample, clean, and potable, with adequate facilities for its distribution in the plant and its protection against contamination and pollution. It must, at a minimum, comply with the National Primary Drinking Water regulations (40 CFR Part 141), be at a suitable temperature, and be under pressure as needed. Every establishment shall make known the source of its water supply and shall afford the opportunity for inspection by a department representative of the water and storage facilities and the distribution system. Establishments using a public water supply shall obtain a letter from the servicing agent stating that the water is tested periodically to determine its potability and that the establishment is supplied water by said agency or company. Establishments using a private water supply shall have the plant water supply tested semi-annually and make the test reports available to the inspector. If the plant uses ice, the ice must be made with potable water meeting the requirements of this subparagraph for the water supply, including testing.
9. Dressing rooms, toilet rooms, and urinals shall be provided in sufficient number and size, be conveniently located, and maintained in a sanitary condition and in good repair. They shall be separate from the rooms and compartments in which products are prepared, stored, or handled.
10. Hand-washing facilities shall be placed in or near toilet, killing, and processing rooms. It is recommended that these are other-than-hand operated, such as knee or photovoltaic.
11. Hand-washing facilities shall be provided and should deliver hot water of at least 105°F and cold water tempered by means of a mixing valve or combination faucet, liquid or powdered soap dispensed from sanitary containers, and individual towels or hand drying devices.

SANITARY FACILITIES

1. Rooms, compartments, all food contact surfaces, equipment and utensils used for preparing, processing, storing, or otherwise handling any product must be cleaned and sanitized as frequently as necessary to prevent insanitary conditions and the adulteration of product.
2. Establishment toilet soil lines shall be separate from other drainage lines to a point outside the building and drainage from toilet bowls and urinals shall not be discharged into a grease catchbasin.
3. Products shall not be processed, prepared, or stored directly beneath sewer lines, drain pipes, or other system carrying sewage or waste unless such pipe lines are leak proof or properly protected by insulating materials or other means.
4. Washing and sanitizing of transportation cages shall be conducted in a separate room or designated area with appropriate drainage. Street cleaning or storage of transportation cages shall be prohibited in public thoroughfares.
5. Operations and procedures involving the dressing, storing, or handling of any livestock carcass or parts thereof shall be strictly in accord with clean and sanitary methods.
6. Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available for review.
7. Animals dressed with hides on shall be thoroughly washed and cleaned before evisceration. Washing equipment of an acceptable type to thoroughly and efficiently wash carcasses inside and out shall be provided.
8. Singeing, where performed, shall be conducted in a sanitary manner to prevent contamination and adulteration of product.
9. Hides shall not be stored on the killing floor, nor stored exposed in rooms or compartments used for edible products.
10. Carcasses with hides on and hunter-killed wild game shall not be stored in contact with skinned and dressed carcasses, parts thereof, or other edible products.

EQUIPMENT AND UTENSILS

1. Equipment and utensils used for slaughtering and dressing livestock or otherwise handling any edible product in any exempt slaughter or exempt processing establishment shall be of such smooth and impervious material and construction as will facilitate their thorough cleaning and ensure cleanliness in the preparation and handling of all edible products to avoid adulteration of such products.
2. Scabbards and similar devices for the temporary retention of knives, steels, triers, etc., by workers and others at exempt slaughter establishments shall be constructed of rust-resistant metal or another impervious material that may be readily cleaned and shall be kept clean at all times.
3. Receptacles used for handling inedible material shall be of such smooth and impervious material and construction that allows them to be easily cleaned and shall be maintained in a clean condition. Such containers shall be conspicuously and distinctively marked "INEDIBLE" and shall not be used for handling any edible product.
4. Live animal and poultry holding and transportation cages shall be thoroughly cleaned and sanitized after use. The holding or storage of unclean transportation cages is prohibited unless these cages are returned to the distributor on the same date received. Establishment live animal and poultry holding cages shall be equipped with waste material catch pans at the bottom of each cage.
5. Tools, equipment, and utensils used for preparing, processing, and otherwise handling of any product shall be made of nontoxic material and shall be thoroughly cleaned and sanitized immediately after a change in processing between species, after any interruption of operations during which time contamination may have occurred, and after each day's use. The equipment shall be properly stored and protected when not in use. All shroud cloths shall be acceptably clean at time of use.
6. All scalders shall maintain acceptably clean water. All scalders shall be emptied, cleaned, and sanitized at least daily.

HUMANE TREATMENT OF ANIMALS

Food animal pens, driveways, and ramps shall be maintained in good repair and free from sharp or protruding objects which may cause injury or pain to the animals. Loose boards, splintered or broken planking, and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired. Floors of food animal pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock.

A covered pen, sufficient to protect livestock from the adverse climatic conditions of the locale, shall be required at those establishments that hold animals overnight or through the day.

Food animals shall have access to water in all holding pens and, if held longer than 24 hours, access to feed. There shall be sufficient room in the holding pen for food animals held overnight to lie down.

Food animals are to be humanely slaughtered, according to established or recognized standards for the particular species. In general, there are two methods of slaughter that are deemed to be humane. The first method requires that livestock are rendered insensible to pain before being shackled, hoisted, cast, or cut. The following guidelines apply:

1. Stunning of food animals shall be accomplished in a manner that will create a minimum of excitement or discomfort for the animal.
2. The driving of food animals to the slaughtering area shall be done with a minimum of excitement and discomfort. Pipes, sharp or pointed objects, and other items which would cause injury or unnecessary pain, shall not be used.
3. Immediately after stunning, the food animals shall be in a state of complete unconsciousness and remain in this condition throughout shackling, sticking, and bleeding.
4. Stunning instruments must be maintained in good repair and available for inspection (air-injection stunning shall be prohibited).

The second method is in accordance with the ritual requirements of any religious faith that prescribes a method of slaughter where the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous severance of the carotid arteries with a sharp instrument. The following guidelines apply:

1. The animals should be restrained and the throat should be cut from side to side with a sharp knife, deeply enough for the major arteries and veins to be severed.
2. The driving of food animals to the slaughtering area and their restraint shall be done with a minimum of excitement and discomfort. Pipes, sharp or pointed objects, and other items which would cause injury or unnecessary pain shall not be used.

Humane slaughter methods may include, but are not necessarily limited to, the following:

- Captive bolt devices
- Electrical stunning
- Gun shot
- Approved ritualistic slaughter procedure (Kosher, Halal, etc.)

PRODUCT PROTECTION

1. Products shall be protected from contamination at all times during production, preparation, storage, and transportation.
2. Refrigerated storage of adequate capacity shall be provided and should be maintained at a temperature not to exceed 41°F for carcasses and parts thereof, processed meats and poultry, meat and poultry by-products, and meat and poultry food products. For the purposes of this section, refrigerated storage of product at a temperature not to exceed 41°F shall include the transportation vehicle used by the exempt operator to deliver product.
3. Vehicles in which products are transported shall be so constructed as to prevent dust, dirt, flies, insects, and other contamination from coming in contact with products and shall be maintained in a clean and sanitary manner. Satisfactory protective covering for products shall be provided when necessary.
4. Carcasses and parts shall be protected from contamination from any source such as dust, dirt, or insects during storage, loading or unloading at, and transportation to and from exempt slaughter establishments. “To protect carcasses and parts from contamination during transport, the product must be enclosed in appropriate packaging material and transported in vehicle compartments with secured, tight fitting doors.”
5. An exempt slaughterer is prohibited from slaughtering for human consumption, cattle that are:
 - Dead or dying
 - Showing clinical signs of Central Nervous System (CNS) disorder
 - Non-ambulatory disabled cattle
6. Specified risk materials (SRMs) shall be removed, as appropriate for the age of the animal, and properly disposed of for all bovines. This is done to prevent the potential spread of Bovine Spongiform Encephalopathy (BSE), commonly referred to as “mad cow disease,” to other cattle and to people. For all cattle, the tonsils and distal ileum (the last 80 inches of the small intestine) shall be removed and disposed of. For all cattle 30

months or older, the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia must also be removed and disposed of. One method that can be used to estimate the age of cattle is by the observation of the animal's teeth or "dentition". More information about dentition is available on FSIS' Policy Development Division's Web page.

7. In species other than cattle, an exempt slaughterer may not slaughter a food animal for human consumption that appears either diseased or injured. This prohibition does not apply to either of the following:
 - The animal owner certifies that the animal was injured within 24 hours prior to slaughter and is otherwise healthy.
 - The exempt slaughter of an animal injured more than 24 hours prior to slaughter where:
 - The animal owner certifies that the animal is injured, is otherwise healthy and
 - A qualified veterinarian performs an ante-mortem and post-mortem examination on the animal and verifies that the animal is healthy at the time of slaughter.
8. An exempt slaughterer shall immediately notify the state veterinarian of the names and addresses of any individuals that have presented animals for slaughter that exhibit central nervous system abnormalities, signs of Foot and Mouth Disease, or other reportable animal health diseases. If such symptoms are encountered, the exempt slaughterer should hold the animal until the state veterinarian has evaluated the animal.

SANITARY OPERATIONS

1. Exempt slaughter and exempt processing establishments shall be maintained in sanitary condition. Each exempt slaughter and exempt processing establishment shall implement and maintain written standard operating procedures for sanitation (SSOPs), when required by state or local authorities, in accordance with the following requirements:
 - The SSOP shall describe all procedures an exempt slaughter or exempt processing establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
 - The SSOP shall be signed and dated by the person with overall authority on site. This signature shall signify that the establishment will implement the SSOP as specified and will maintain the SSOP in accordance with the requirements of this part. The SSOP shall be

signed and dated upon initially implementing the SSOP and upon any modifications to the SSOP.

- Procedures in the SSOP that are to be conducted prior to operations shall be identified as such and shall address, at a minimum, the daily cleaning of food contact surfaces of facilities, equipment, and utensils.
- The SSOP shall specify the frequency with which each procedure in the SSOP is to be conducted by the exempt processor and identify the employee(s) responsible for the implementation and maintenance of such procedure(s).
- Each exempt slaughter and exempt processing establishment shall conduct the pre-operational procedures in the SSOP before the start of operations and shall conduct all other procedures as specified in the SSOP.
- The owner or operator of the exempt slaughter or exempt processing establishment shall monitor the daily implementation of the SSOP.
- The operator of the exempt slaughter or exempt processing establishment shall evaluate the procedures contained in the SSOP to prevent direct contamination or adulteration of product(s) and shall revise the SSOP as necessary to keep the procedures effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.
- The operator of the exempt slaughter or exempt processing establishment shall take appropriate corrective action(s) when either the establishment or department representative determines that the establishment's SSOP failed to prevent direct contamination or adulteration of product(s). Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the SSOP.
- Each exempt slaughter and exempt processing establishment shall maintain daily records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employee(s) specified in the SSOP shall authenticate the record with his or her initials and the date. These records shall

be maintained for at least six months and made available to a department representative upon request. All such records shall be maintained at the exempt slaughter or exempt processing establishment.

2. In establishments where poultry is processed, chilling tanks or vats shall be of smooth construction. They shall have a continuous water overflow and be emptied, cleaned, and sanitized after each use. Poultry carcasses and parts thereof not immediately given to the consumer shall be chilled after evisceration to an internal temperature not to exceed 41°F prior to shipment.
3. Poultry scalders shall maintain acceptably clean water. Poultry scalders shall be emptied, cleaned, and sanitized at least daily.
4. Eviscerating facilities and equipment must be sufficient at each workstation to insure that carcass and product preparation can be accomplished without contamination.
5. Carcasses, parts thereof, and meat and meat food products that are adulterated and/or not returned to the owner shall be adequately denatured or decharacterized to preclude their use as human food. Before the denaturing agents are applied, carcasses and carcass parts shall be freely slashed or sectioned. The denaturing agent must be mixed with all of the carcasses or carcass parts to be denatured and must be applied in such quantity and manner that washing or soaking cannot easily and readily remove it. A sufficient amount of the appropriate agent shall be used to give the material a distinctive color, odor, or taste, so that such material cannot be confused with an article of human food.

PERSONNEL

1. All persons working in contact with product, food contact surfaces, and product packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.
2. Aprons, frocks and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day, and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.
3. Any person who has, or appears to have, an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations

which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

4. Personnel responsible for identifying sanitation failure or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Personnel and supervisors responsible for slaughter or processing should receive appropriate training in proper food protection principles.

MEAT ESTABLISHMENTS PROCESSING WILD GAME

A meat establishment may *custom process* legally harvested wild game for the game owner if all the following apply:

- The meat establishment operator notifies the regulatory agency, which may restrict wild game processing that is incompatible with the exempt slaughter or exempt processing food animals at the establishment.
- The operator accepts only clean and apparently wholesome wild game carcasses for custom processing.
- The operator processes wild game only at times when the operator is not slaughtering or processing food animals.
- The operator cleans and sanitizes equipment used to process wild game before using that equipment to slaughter or process food animals.
- The operator keeps wild game and wild game products separate from all other meat and meat food products in the establishment.
- The operator clearly labels wild game products, so they cannot be confused with other meat or meat food products. Wild game products must clearly be identified by species.

RECORDS AND CONTROLS

1. The operator or owner of the exempt slaughter or exempt processing establishment shall take appropriate corrective action(s) when either the establishment or regulatory agency determines that the establishment's SSOP failed to prevent direct contamination or adulteration of product(s). Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the SSOP.

2. Each exempt slaughter and exempt processing establishment shall maintain daily records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employee(s) specified in the SSOP shall authenticate these records with his or her initials and the date. These records shall be maintained for at least six months and made available to a regulatory agency representative upon request. All such records shall be maintained at the exempt slaughter or exempt processing establishment.
3. Custom slaughter records shall contain the name, address, and telephone number of the owner of each food animal slaughtered, the date the food animal was slaughtered, the species and brief description of the food animal, and in the case of bovines, the age of the animal as either under 30 months or 30 months or older and how the age was determined (documentation provided by the animal owner or examination of dentition). The ambulatory status of each bovine animal shall also be recorded as well as the proper disposition of all specified risk materials (SRMs).
4. Additional records that must be kept include records such as bills of sale, invoices, bills of lading, and receiving and shipping papers for transactions in which any food animal or carcass, meat or meat food product is purchased, sold, shipped, received, transported, or otherwise handled by the exempt slaughter or exempt processing establishment.
5. Operators of facilities conducting exempt slaughter and exempt processing shall keep slaughter and processing records for a period of two years, beginning on January 1 of the previous year plus the current year to date.
6. All records shall be available to regulatory agency representatives on request.
7. A regulatory agency representative may attach a "Reject Tag" to any equipment, utensil, room, or compartment at an exempt slaughter or exempt processing establishment that he or she determines is insanitary and presents a health hazard. No equipment, utensil, room, or compartment so tagged shall again be used until untagged or released by a regulatory agency representative. Such tag so attached shall not be removed by anyone other than a regulatory agency representative.
8. A regulatory agency representative that determines any meat is adulterated, unfit for human food, from an unhealthy or unsound animal or may be a health hazard, may attach a "Retain Tag" to the meat and document the reason for attaching the tag on a form specified by the

regulatory agency and deliver the form to the operator of the meat establishment. The owner of the meat shall be notified by the plant operator and advised of the potential health risk.

The custom processor shall ensure that the owner of the meat either authorizes the voluntary destruction and denaturing of the meat or agrees to remove the meat from the custom processing establishment. Under no circumstances may the meat be further processed at the establishment.

9. Safe handling labeling or instructions shall accompany every customer's raw or not-fully-cooked products.

Safe Handling Instructions

Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe-handling instructions.



Keep refrigerated or frozen.
Thaw in refrigerator or microwave.



Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.



Cook thoroughly.



Keep hot foods hot. Refrigerate leftovers immediately or discard.

10. A person who slaughters any food animal for human consumption or who processes the meat of any food animal for human consumption, must keep records including:
 - The date of slaughter or processing.
 - The number and type of animals slaughtered and the disposition of the carcasses.
 - The type and amount of meat processed and the disposition of that meat.
 - Certificates signed by persons submitting injured animals for slaughter. (See Section "Product Protection" #5 and #6).

The person must keep the records for at least two years and make the records available for inspection and copying by the regulatory agency upon request.

11. Meat that is prepared on a custom basis shall be marked at the time of preparation with the term, "Not for Sale", in letters at least three-eighths of an inch in height and shall also be identified with the owner's name or a code that allows identification of the carcass or carcass part to its owner. Only approved ink shall be used for marking such products.
12. Exempt slaughtered or exempt processed poultry prepared for further distribution for sale must be labeled to include the producer's name and address and the statement, "Exempted – P.L. 90-492" or other regulatory agency requirement.
13. A person performing a mobile custom slaughter must return the resulting meat to the service recipient at the slaughter site, except that the service provider may transport carcasses, other than poultry carcasses, to a licensed or registered meat establishment for custom processing. Carcasses must be transported in a sanitary manner and must be conspicuously marked, "Not for Sale."

A person providing mobile custom slaughter or processing services must keep records including:

- The name and address of each service recipient.
 - The number and type of animals slaughtered for each service recipient.
 - The date of each slaughter.
 - The disposition of each carcass. If a carcass is transported to another location for further processing, the report must identify that location.
14. If a custom exempt facility needs to transport cattle carcasses with SRMs for removal and further processing to another custom exempt facility, it may do so if the owner directs in writing that this movement occurs. Each custom facility should have a copy of the owner's written communication as evidence of the owner's continuing control.

PRESCRIBED TREATMENT OF HEAT-TREATED EXEMPT PROCESSED MEAT

1. All forms of exempt processed fresh meat, including fresh unsmoked sausage and pork, such as bacon and jowls, are classified as products that are customarily well cooked in the home before being consumed. Therefore, the treatment of such products for the destruction of pathogens is not required.

2. Exempt processed meat that is not customarily cooked or may not be cooked before consumption, because it has the appearance of being fully cooked, must not contain pathogens. These products shall be effectively heated, refrigerated, or cured to destroy any possible live trichinae using one of the methods described in 9 CFR 318.10.
3. All ready-to-eat (RTE) products must be heated with humidity to an internal temperature according to the following chart:

Internal Temperature Degrees F	Time	Internal Temperature Degrees F	Time
130	112 min.	145	4 min.
131	89 min.	146	169 sec.
132	71 min.	147	134 sec.
133	56 min.	148	107 sec.
134	45 min.	149	85 sec.
135	36 min.	150	67 sec.
136	28 min.	151	54 sec.
137	23 min.	152	43 sec.
138	18 min.	153	34 sec.
139	15 min.	154	27 sec.
140	12 min.	155	22 sec.
141	9 min.	156	17 sec.
142	8 min.	157	14 sec.
143	6 min.	158	0 sec.**
144	5 min.		

**The required lethalties are achieved instantly when the internal temperature of a cooked meat product reaches 158°F or above.

4. Heat-treated products that must be stored under refrigerated temperatures must be cooled quickly to prevent bacterial growth. During cooling, the product's maximum internal temperature should not remain between 130 degrees Fahrenheit and 80 degrees Fahrenheit for more than 1-1/2 hours nor between 80 degrees Fahrenheit and 41 degrees Fahrenheit for more than 5 hours. Exempt processors may slowly cool cured products in accordance with Food Safety and Inspection Services (FSIS) Directive 7110.3, Time/Temperature Guidelines for Cooling Heated Products.
5. Exempt processors not utilizing a heating step as described in Paragraphs 2 or 3 above must submit an alternate procedure, describing the method utilized in determining safety to the state regulatory agency.

6. When necessary to comply with the heat treatment requirements of this section, the smokehouses, drying rooms, and other compartments used in the treatment of exempt processed meat products to destroy pathogens shall be suitably equipped by the operator of the exempt processing establishment with accurate automatic recording thermometers.
7. All ready-to-eat exempt processed pork products shall have undergone a formulation, temperature, or curing process designed to eliminate trichinae. This may include freezing as prescribed in FSIS 318.10, heating to 144°F minimum or through a process which includes controlling the size of the chopped meat in the product, ensuring a specific salt content, and specifying the length of time in a drying room at a specific temperature.

Retail Meat and Poultry Processing Guidelines, Revised June 2011

INTRODUCTION

AFDO is pleased to make these guidelines available in response to requests from state and local government agencies to provide them guidance on the processing of meat and poultry products at retail. AFDO finds that guidance currently available to regulatory officials on commercial practices and regulatory surveillance in this area of retail operations is sparse and inconsistent.

These guidelines provide sound scientific support for the production of unique meat and poultry products such as dry and semi-dry fermented sausage, meat jerky, and cured and smoked meat and poultry.

These guidelines are intended to promote greater uniformity in the regulation of these products. Accordingly, these guidelines reflect AFDO-recommended best practices that are consistent with USDA requirements for these products under federal laws.

The guidelines have been reviewed and approved by members of the AFDO Meat and Poultry Committee, AFDO Retail Food Committee, and the AFDO Board of Directors, in cooperation with the U.S. Department of Agriculture, Food Safety and Inspection Service.

I. USDA-FSIS RETAIL EXEMPTION

The mandatory inspection requirements of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) do not apply to the preparation of meat and poultry products traditionally and usually conducted at retail stores, when conducted at retail stores in normal retail quantities.

These exemptions are found in 9 CFR 303.1(d) for red meat and 9 CFR 381.10(d) for poultry. It is important to note that the adulteration and misbranding provisions of the FMIA and PPIA other than the requirement of the official inspection legend do apply to articles that are exempted from inspection. In order to qualify for these exemptions the following requirements must be met.

A. Red Meat

1. Operations of types of traditionally and usually conducted at retail stores are the following:
 - (a) Cutting up, slicing, and trimming carcasses, halves, quarters, or wholesale cuts into retail cuts such as steaks, chops, roasts, and freezing such cuts;
 - (b) Grinding and freezing products made from meat;

- (c) Curing, cooking, smoking, rendering or refining of livestock fat or other preparation of products, except slaughtering or the retort processing of canned products;
 - (d) Breaking bulk shipments of meat products;
 - (e) Wrapping or rewrapping meat products.
2. Normal Retail Quantity—As described in 9 CFR § 303.1(d)(2)(ii), the normal retail quantity is not more than one-half carcass. This section further provides examples of the amount of product that will be accepted as representing one-half carcass for different species, which are as follows:
- (a) Cattle – 300 pounds
 - (b) Swine – 100 pounds
 - (c) Calves – 37.5 pounds
 - (d) Sheep – 27.5 pounds
 - (e) Goats – 25 pounds
3. Retail Stores—The requirements to qualify as a retail store are listed in 9 CFR § 303.1(d)(2)(iii). These requirements are as follows:
- (a) The sales of meat products are made to consumers only;
 - (b) At least 75 percent, in terms of dollar value, of total sales of meat product represents sales to household consumers, and the total dollar value of sales of product to consumers other-than-household consumers does not exceed the dollar limitation per calendar year set by the FSIS Administrator;
 - (c) Only federally or state inspected and passed meat product is handled or used in the preparation of any product;
 - (d) No sale of meat product is made in excess of a normal retail quantity as described in Part I. A. 2;
 - (e) The preparation of meat products for sale to household consumers is limited to the operations listed in Part I. A. 1. of this section;
 - (f) The preparation of meat products for sale to other-than-household consumers is limited to the operations described in Part I. A. 1. (a), (b), (d), and (e).
4. Retail Sales—The sale of meat products produced in a retail store under the exemption from inspection requirements described in 9 CFR § 301.1(d) is limited to household consumers or hotels, restaurants, or institutions (HRI) only. The term “consumer” is defined in 9 CFR § 303.1(d)(2)(vi) as “any household consumer, hotel, restaurant, or similar institution as determined by the Administrator in specific cases”.

B. Poultry Products

1. Operations of types traditionally and usually conducted at retail stores include any processing of poultry products, except canning and slaughtering of poultry, unless such slaughtering is conducted on live poultry purchased at the retail store and processed by the retail store operator in accordance with the consumer's instruction.
2. A normal retail quantity is any quantity of a poultry product purchased by a household consumer from a retail supplier that does not exceed 75 pounds. A normal retail quantity sold by a retail supplier to other than a household consumer is any quantity that does not exceed 150 pounds.
3. A retail store is a place of business where:
 - (a) The sales of poultry products are made to consumers only;
 - (b) At least 75 percent, in terms of dollar value, of total sales of poultry product represents sales to household consumers, and the total dollar value of sales of product to consumers other-than-household consumers does not exceed the dollar limitation per calendar year set by the FSIS Administrator;
 - (c) Only federally or state inspected and passed poultry product is handled or used in the preparation of any product;
 - (d) No sale of poultry product is made in excess of a normal retail quantity as described in Part I. B. 2;
 - (e) The preparation of poultry products to household consumers is limited to the operations listed in Part I. B. 1. of this section.

C. Recordkeeping Requirements

Any retail store claiming exemption under 9 CFR § 303.1(d) must maintain complete, accurate, and legible records of total monthly purchases and of total monthly sales of meat, meat byproducts, and meat food products in terms of dollar values of the products involved. These records must also separately show total sales to household consumers and total sales to other-than-household consumers. These recordkeeping requirements are detailed in 9 CFR § 303.1(d)(3). These records are required to be maintained for a period of two years after December 31 of the year in which the transaction has occurred and for any further period as FSIS may require for purposes of any investigation or litigation by written notice to the person required to keep these records as described in 9 CFR § 320.3.

D. Adulteration and Misbranding

The adulteration and misbranding provisions of the Federal Meat Inspection Act and 9 CFR Part 300 to end, other than the requirement of the official inspection legend, apply to articles which are exempt from inspection, or not required to be inspected. This includes the requirement

that any pork and any product containing pork be prepared only in compliance with any applicable requirement for the destruction of trichina, as provided in 9 CFR § 318.10.

All meat products produced at a retail store for sale to other-than-household consumers must be labeled in accordance with the requirements of 9 CFR Part 317. Each package or container is required to show the following information:

- (a) The name of the product;
- (b) If the product is fabricated from two or more ingredients, the word “ingredients,” followed by a list of the ingredients as prescribed in 9 CFR § 317.2(f);
- (c) The name and place of business of the retail store;
- (d) An accurate statement of the net quantity of contents;
- (e) Safe handling instructions as described in 9 CFR 317.2(l).

The Secretary of Agriculture may extend the requirements of the Federal Meat Inspection Act to any establishment where meat products are prepared for distribution, if it is determined that, in accordance with the adulteration provisions of the Act, the establishment is producing adulterated products which would clearly endanger the public health.

E. Commonly Asked Questions Concerning the Retail Preparation of Red Meat Products

1. Q: *What is the sales limit for products prepared at retail for sale to other-than-household consumers?*

A: There are two caps on the sales of products prepared at retail for sale to other-than-household consumers, which cannot be exceeded. No more than 25 percent of the total red meat sales of a retail store can be made to other-than-household consumers. In addition, the total red meat sales to other-than-household consumers cannot exceed the dollar limitation per calendar year set by the FSIS Administrator.

2. Q: *Where can I obtain the dollar limitation per calendar year set by the FSIS Administrator?*

A: The dollar limitation is adjusted during the first quarter of each calendar year. Notice of the adjusted dollar limitation is published in the FEDERAL REGISTER. This information is available on the USDA-FSIS website.

3. Q: *Can a retail store produce multi-ingredient meat products for sale to other-than-household consumers?*

A: Yes, provided that the operation will not have a definitive effect on the nature or safety of the product, and that the product is properly

labeled with all of the ingredients listed. However, the addition of a curing agent to Italian sausage would affect the nature of the sausage, as well as its safety, and the modified sausage would need to be named to reflect the fact that it is cured, and it would not be eligible for sale to other-than-household consumers.

4. Q: *Can a retail store produce a meat product that is cured, cooked, smoked, or rendered or refined livestock fat for sale to other-than-household consumers?*

A: No, any of these operations would have a definitive effect on the nature of the product and would have to be produced under either federal or state inspection.

5. Q: *Can a retail store produce a meat product that is cured, cooked, smoked, or rendered or refined livestock fat for sale to household consumers?*

A: Yes, a retail store can produce and sell these types of meat products to household consumers only and are limited to normal retail quantities.

6. Q: *Can a retail store slice inspected ready-to-eat meat products for sale to other-than-household consumers?*

A: Yes, this operation would not have a definitive effect on the nature of the product and is allowed under the exemption in 9 CFR § 303.1(d).

7. Q: *Do meat products produced at a retail store need to be labeled?*

A: Yes, the Federal Meat Inspection Act provides that the adulteration and misbranding provisions of the Act, other than the requirement of the inspection legend, shall apply to articles which are not required to be inspected.

8. Q: *Can meat products produced at a retail store be sold to another retail store or to a distributor or wholesaler?*

A: No, meat products produced at a retail store can only be sold to household consumers, hotels, restaurants, or similar institutions.

9. Q: *Can meat products produced at a retail store be sold on the internet and shipped in interstate commerce?*

A: Yes, provided that the sales are to consumers, as defined in 9 CFR § 303.1(d)(2)(vi), and that the meat components used in the products were federally inspected. State inspected meat products can only be distributed intrastate and cannot move in interstate commerce by virtue of the fact that they were further processed in a retail store.

II. GROUND MEATS

A. Definitions

1. "Beef Pattie Mix" or "Beef Patties" if in pattie form, means chopped, or mechanically separated ground beef, or partially defatted beef fatty tissue with or without the addition of beef fat. Binder or extenders may be used without added water or with added water only in an amount such that the product's characteristics are essentially that of a meat pattie.
2. "Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing.
3. "Grinder" means a piece of equipment used to cut meat into small pieces. The meat is fed from a hopper and passed along a cylinder with an auger or worm to a perforated plate where it is sliced away by revolving blades.
4. "Ground Beef" means chopped or ground beef with or without seasoning and without the addition of beef fat, and as such, shall not contain more than 30 percent fat and shall not contain added water, phosphates, binders, or extenders.
5. "Ground Poultry Meat" means chopped or ground poultry without the addition of water, cereal, soy derivatives, or other extenders and with no more than 15 percent skin.
6. "Hamburger" means chopped fresh or frozen beef with or without the addition of beef fat, and/or seasoning, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders.

B. Grinding

1. Whenever a grinder is temporarily stored with the intent of using it again in the very near future, the grinder head and hopper must be refrigerated at 41°F or less until used again.
2. Grinding equipment shall be completely disassembled and cleaned by washing, rinsing, and use of an approved sanitizer after each use or at least daily.
3. If the species of meat being ground or comminuted is changed from one batch to the next, the entire grinding assembly must be dismantled and cleaned.

4. When beef cheek meat (trimmed beef cheeks) is used in the preparation of chopped beef, ground beef, or hamburger, the amount of cheek meat shall be limited to 25 percent. If used in excess of natural proportions, it must be identified on the label.

C. Time-Temperature Control During Grinding and Trimming

Trimmings to be used for ground meat shall be held at 41°F or less (product temperature) during the trimming process. Ground beef and ground poultry shall be held at 41°F or less at all times during grinding, storage, or display.

D. Labeling Ground Meat Products

1. The common or usual name of any added ingredient shall be listed on the package label in decreasing order of predominance or on a placard when displayed in bulk. Binders, extenders, and water, if added to beef pattie mix or beef patties, must be clearly identified on the label or placard.
2. An added descriptive name may be used where the ground meat is prepared entirely from a specific cut such as chuck, round, or sirloin (example: ground beef sirloin). When beef trimmings are used in the mixture, it may only be labeled as ground beef or hamburger.
3. The fat content or lean content shall be clearly indicated on the label. The fat content shall not exceed 30 percent. Whenever the terms "lean," "extra lean," or "reduced fat" are used, the product and labeling must be in compliance with NLEA requirements listed in the Code of Federal Regulations.
4. "Previously Frozen" must be labeled on the package, container, or wrapping if a meat/meat food product or poultry/poultry food product has been frozen prior to sale.
5. The label shall contain a code date to identify the batch or lot.
6. A "Safe Handling Statement," as defined by USDA Meat and Poultry Regulations §317(2)(1) and §381.125(b), shall be fixed to the package where it is easily visible to the consumer.

E. Recordkeeping

Records that identify suppliers of source material used in the preparation of each lot of raw ground or chopped beef product shall be maintained by the retail establishment. Records shall include the following information:

1. Retail operation's name and address (city, state, zip code)
2. Product information
 - (a) Date and time product was ground
 - (b) Exact name and type of store-ground product
 - (c) Quantity of product ground
 - (d) Production code of each lot of store-ground product
 - (e) Sell-by or use-by dates
 - (f) Other information used to identify the store-ground product
3. Source (supplier) information
 - (a) Supplier name and address (city, state, zip code)
 - (b) USDA Establishment Number for each source material used
 - (c) Product name
 - (d) Production date and lot number
4. Cleaning/Sanitizing information (example: date/time, especially significant between varied source materials)

F. *E. coli* O157:H7 Sampling by Meat Inspection Investigators

Federal or State Meat Inspection Investigators are instructed to collect a raw ground beef sample, during operating hours, when the retail store is grinding or has ground product that is still available at the retail store, under one or more of the following circumstances:

1. Grinding primal, subprimals, or boxed beef;
2. Grinding store generated bench trim derived from its own operations;
3. Grinding beef that is labeled "natural" or "all-natural"

Samples are not collected from product that is:

- (a) Case ready (example: consumer-sized packages of ground beef, which were packaged at the official establishment);
- (b) Not ground by the retail store but only portioned into retail trays;
- (c) Reground product (i.e., course ground product from the official establishment which is reground by the retailer into finely ground product);
4. Not cleaning and sanitizing the grinder between the use of different source materials;
5. Grinding purchased trim that is not accompanied by records of negative test results for *E. coli* O157:H7;

6. Using meat cuts (steaks or roasts that the store determines are suitable as an ingredient in raw ground beef) with expired sell-by dates;
7. Grinding and failing to keep records of the federal or state establishment numbers of its suppliers;
8. Mixing irradiated and non-irradiated beef.

III. CURING AND SMOKING

A. Definitions

1. "Acceptable Product List" means a list of meat or poultry products for which a HACCP Plan has been validated by a process authority.
2. "Casings" mean natural animal stomachs, intestines or bladders or manufactured casings of cellulose or collagen, which are used to contain comminuted meat, or poultry product mixtures for sausages.
3. "Cold Smoking" means a smoking process used to apply smoke or a smoke flavor at or near ambient temperature to food products not sufficiently darkened or flavored in the original cooking process.
4. "Critical Limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.
5. "Curing" means the development of a characteristic pink color in meat based on the interaction of nitrite and meat pigments or other physical processing.
6. "Cure Accelerator" means compounds, such as ascorbic acid or erythorbic acid or their derivatives, sodium ascorbate and sodium erythorbate, as defined for use in 9 CFR 424.21(c), which shorten the time required for the distinctive pink color to develop in cured meat and poultry products.
7. "Food Safety Hazard" means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
8. "HACCP Plan" means a written document that delineates the formal procedures for following the Hazard Analysis and Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods.

9. "Injection" means the process of transferring a curing solution into a whole muscle meat using a needle or group of needles connected to a brine source.
10. "Massaging" means subjecting meat chunks to a mechanical treatment to facilitate protein extraction from muscle fibers. This process accelerates the even dispersal of cure solution and increases yield.
11. "Showering" means a potable water spray with or without liquid smoke in the smoke house, which, depending on when the water spray is applied, maintains humidity and flavors, decreases cooking time, promotes rapid cooling, or reduces casing shrinkage.
12. "Smokehouse" means a piece of equipment or room sized enclosure used to conduct the smoking and cooking process which has a smoke source, adequate ventilation, heat and humidity source if necessary, approved plumbing and waste lines if necessary, support structures for the food products to be smoked and a method to determine internal product temperature.

B. Trained Employees

All employees engaged in the curing and smoking process shall receive training and demonstrate familiarity with the curing and smoking processes as well as the associated hazards.

C. HACCP Plan

Each retail food establishment that engages in the curing and smoking process must have a HACCP plan validated by a process authority. This HACCP plan must be made available to the regulatory authority for review and audit. The HACCP Plan must contain process flows for each category of product, recipe formulations for each product that is cured and/or smoked, critical limits, identified hazards, monitoring procedures, corrective action and verification steps. It must include an acceptable products list, which has received approval under the HACCP Plan. It shall also contain a description of the training course content for employees engaged in the curing and smoking operation.

D. Equipment and Materials

1. A calibrated automatic recording thermometer with internal product temperature probes or calibrated metal-stemmed thermometer shall be available and used when product is smoked.
2. Calibrated and certified scales shall be used to weigh any curing compound, cure accelerator, or other additive, provided it has not already been premeasured and weighed.

3. Tumble massagers facilitate the extraction of salt soluble proteins and accelerate the distribution of cure solution in chunks of meat. Massaging must be done under refrigeration, recommended at 33° to 36°F.
4. All equipment coming in contact with meat products must be fully cleaned by washing, rinsing, and use of an approved sanitizer.
5. A smoke generator attached to a smokehouse may only use materials approved by USDA, FDA, or other regulatory agencies. These materials include non-resinous hardwoods, hardwood sawdust, redwood, mesquite wood, corncobs, and natural liquid smoke.
6. Natural or artificial casings for sausage, loaf, or chub forming must be sanitary and may not be stripped for reuse with another batch or lot. The casings may be salted or unsalted, colored or shirred, that is, pleated or compressed for easy application to the stuffing horn.
7. Curing or smoking may not be used to salvage meat or poultry that has excessive bacterial growth or spoilage.

E. Time-Temperature Control During Curing

1. The curing process, using immersion and injection, shall be done so that product temperature remains at 41°F or less.
2. Meat and poultry products, as well as natural and artificial casings, during soaking shall be stored at 41°F or less.
3. The internal temperature of any smoked meat or poultry or smoked meat or poultry product shall comply with cooking requirements for that product, with the exception that:
 - (a) Cold smoking is a smoking process used only to apply smoke color or flavor at ambient temperature to food products; and
 - (b) When a cold smoking process is used for cosmetic purposes, that is, to add smoke color or flavor to pre-cooked product, it must be of such duration that the internal product temperature remains at or below 41°F.

F. Curing Process

1. Use of curing agents, curing accelerators, and other additives shall be according to 9 CFR 424.21(c), Use of Food Ingredients and Sources of Radiation.
2. The formulation and preparation procedure must be documented by lot.

G. Curing Methods

1. "Dry curing" means all surfaces of the meat are rotated and rubbed at intervals of sufficient frequency to assure cure penetration.
2. "Dry salt curing" is a modification of the dry curing method where the product may be injected with cure solution directly into the muscle tissue before the dry salt cure is rubbed onto the surface.
3. "Immersion curing" introduces the cure solution by osmosis. The pickle or brine solution requires periodic mixing to facilitate uniform curing. Immersion curing solutions shall be discarded after each use except when they remain with the same batch or lot during the entire curing process.
4. "Injection curing" introduces the curing solution into the muscle meat through hollow needles.
 - (a) "Stitch pumping" injects the curing solution deep into the muscle with a single orifice needle.
 - (b) "Spray pumping" injects the curing solution using a needle with many orifices to allow more uniform distribution of the solution.
 - (c) "Artery pumping" injects the curing solution into the natural circulatory system of the meat.
 - (d) "Machine pumping", similar to "stitch pumping," injects the curing solution using 10 or more needles.
 - (e) Sometimes spring-loaded needles are used for bone-in products to prevent breaking the needles.

H. Time-Temperature Control During the Smoking Process

1. The smoking process shall be considered equivalent to a cooking process and be required to meet all internal time-temperature cooking requirements. This information shall be documented for each lot.
2. Cold smoked meat and poultry products shall be processed at or near ambient temperature so that the internal product temperature does not rise above 41°F. The product and air temperature shall be monitored at all times.
3. Hot smoked meat and poultry products shall be cooled to 70°F within 2 hours and to 41°F or less within an additional 4 hours. Or, as an alternative, The Stabilization Guidelines for 9 CFR 318.17(b) can be strictly followed. These guidelines are available on the FSIS web site.
 - (a) If cold water showering is used to rapidly drop product temperature after smoking, it must be potable water, contain a chlorine residual, may not be recirculated unless by an approved method, and if reclaimed, must be discarded daily.

- (b) Cooling times and temperatures must be documented for each lot, but in all cases, it must reach 140°F to 70°F internal product temperature within 2 hours and from 70°F to 41°F or below within and additional 4 hours.

I. Storage of Smoked Product

Ready-to-eat smoked product must be stored in a manner and location to prevent cross- contamination or adulteration.

IV. DRY AND SEMI-DRY FERMENTED SAUSAGE

A. Definitions

1. "Dry Fermented Sausage" means a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and is then dried to remove 25-50 percent of the moisture to have a moisture/protein ratio in compliance with USDA requirements. Dry fermented sausages include summer sausages, salamis, and pepperonis.
2. "Fermentation Culture" means an active and pure culture of one or more bacteria, which effects the rapid pH drop in dry and semi-dry fermented sausages.
3. "**Process Authority**" means a person or institution with expert knowledge and experience to make determinations about the safety of a food process and formulation.
4. "Semi-Dry Fermented Sausage" means a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and undergoes up to 15 percent removal of moisture during the fermentation/heating process. Semi-dry fermented sausages include thuringer, cervelat, and Lebanon bologna.

B. Validation of Processing Procedure for Dry and Semi-Dry Fermented Sausages

In light of foodborne outbreaks of *E.coli* O157:H7 linked to dry fermented ready-to-eat sausage products, all procedures for dry and semi-dry fermented sausages must be validated to show products achieve a 5-log reduction of *E.coli* O157:H7. Full documentation is required. This can be accomplished by using one or more of the following options:

1. Submit the processing procedure to a recognized process authority for validation.

2. Design and conduct validation studies utilizing a laboratory that is certified for testing pathogenic bacteria in meat and poultry products including any non-food manufacturing biosafety level II facility.
3. Modify processing procedures to include a moist heating step after fermentation but prior to drying. The moist heating can be accomplished by using a sealed oven or steam injection to raise the relative humidity above 90 percent throughout the cooking process and meet one of the following time-temperature requirements:

Min. °F Internal Temp.	Min. Holding Time at that Temp.
130	121 min.
131	97 min.
132	77 min.
133	62 min.
134	47 min.
135	37 min.
136	32 min.
137	24 min.
138	19 min.
139	15 min.
140	12 min.
141	10 min.
142	8 min.
143	6 min.
144	5 min.
145	4 min.

4. Examples of processes that yield a 5 D or more reduction of *E. coli* O157:H7:
 - (a) Ferment at 90°F to pH 5.3 and apply cook, then dry for >7 days (large casing).
 - (b) Ferment at 90°F to pH 4.6 and hold at 90°F for >6 days (small casings).
 - (c) Ferment at 90°F pH 4.6 and apply cook (small and large casings).
 - (d) Ferment at 110°F to pH 4.6 and hold at 110°F for >4 days (small and large casings).
5. Initiate a hold and test program, unless the source of the ingredients as been certified pathogen free. This involves the holding and testing of all batches of dry and semi-dry sausages. Samples must be submitted to a laboratory that is certified for testing pathogenic bacteria in meat and poultry products.

6. Implement a HACCP plan combined with Good Manufacturing Practices (GMPs) for fermented sausage, including raw batter testing and documentation of at least a 2 D lethality of *E. coli* O157:H7 between stuffing and shipping.
 - (a) An acknowledged analytical method equivalent to that used by USDA/FSIS must be implemented in the raw batter testing.
 - (b) The sample size and composting procedure must ensure a detection level of 1-gm. (It is recommended that fifteen 25-gm. samples be taken from across the lot. These could then be composited into five, 75-gm. analytical samples.)
 - (c) The definition of a "lot," for the purposes of sampling, must be statistically sound.
 - (d) GMPs must be applied throughout the process.
 - (e) The HACCP plan must also address pathogen issues concerning *Salmonella*, *Trichinella*, *E. coli* O157:H7, and *Staphylococcus*.
 - (f) A procedure for dealing with lots from positive batter samples must be defined in the HACCP plan. At a minimum, all positive lots must be subjected to conditions that will provide a total 5 D process.

C. Fermentation Cultures

1. If a commercially prepared fermentation culture is used, any special handling instructions specified by the manufacturer regarding frozen or refrigerated storage and other factors must be observed.
2. If a back inoculum from a previously fermented and controlled mother batch is used, the mother batch shall have attained a pH of 5.3 and shall be monitored on a regular basis for lactic acid producing bacteria and coagulase positive staphylococci.

D. Fermentation Time-Temperature Control

Once the pH reaches 5.3 or less during fermentation by lactic acid bacteria, the potential for *Staphylococcus aureus* growth is effectively controlled, thus minimizing the ability for growth to a dangerous level. During fermentation of sausages, it is necessary to limit the time during which the sausage meat is exposed to temperatures exceeding 60°F or higher which is the critical temperature at which staphylococcal growth effectively begins.

1. Degrees/Hours Defined*
 - (a) Fewer than 1200 degree/hours when the highest fermentation temperature is less than 90°F.
 - (b) Fewer than 1000 degree/hours when the highest fermentation temperature is between 90°F and 100°F.

- (c) Fewer than 900 degree/hours when the highest fermentation temperature is greater than 100°F.

***Note:** Degrees are measured as the excess over 60°F at which staphylococcal growth effectively begins. Degree/Hours are the product of time in hours at a particular temperature and the "degrees."

Degree/Hours are calculated for each temperature used in the process. The limitation of the number of degree/hours indicated in a, b, and c, depend upon the highest temperature in the fermentation process prior to the time that a pH of 5.3 or less is attained. Processes exceeding 89°F prior to reaching a pH of 5.3 are limited to 1000 degree/hours; processes exceeding 100°F prior to reaching pH 5.3 are limited to 900 degree/hours.

2. Temperature measurements should be taken at the surface of the product. Where this is not possible, fermentation room temperatures should be utilized.
3. Constant Temperature Processes — The time-temperature relationships for constant temperature processes, predicated on fermentation room temperatures, are as follows:

Degree/Hour	Temperature (°F)	Allowed Hours
1200	75	80
1200	80	60
1200	85	48
1000	90	33
1000	95	28
1000	100	25
900	105	20
900	110	18

EXAMPLES OF CONSTANT TEMPERATURE PROCESSES

Process A. Constant 80°F temperature for 55 hours with pH decline to 5.3

Degrees: $80 - 60 = 20$

Hours: 55

Degree/Hours: $(20) \times (55) = 1100$ degree/hours

Process A Passes

Process B. Constant 90°F temperature for 40 hours with a pH decline to 5.3
 Degrees: 90 – 60 = 30
 Hours: 40
 Degree/Hours: (30) x (40) = 1200 degree/hours
Process B Fails (Limit: 1000 degree hours)

4. Variable Temperature Processes—In testing each process, each step-up in the progression is analyzed for the number of degree/hours it contributes, with the highest temperature used in the fermentation process determining the degree/hour limitation as follows:

Process C.

Hours	Temp.(°F)	Critical Temp. Adjustment	Degrees	Degree/Hours
10	75	75-60	15	150
10	85	85-60	25	250
16	95	95-60	35	560
pH = 5.3				Total = 960

Process C Passes

Process D.

Hours	Temp.(°F)	Critical Temp. Adjustment	Degrees	Degree/Hours
10	75	75-60	15	150
10	85	85-60	25	250
18	98	98-60	38	684
pH = 5.3				Total = 1084

Process D Fails because the limit is set at 1000 degrees/hours for times and temperatures and it has taken 1084 degrees/hour to attain pH 5.3.

5. Lots Falling Outside Limitations—Once a processing schedule has been developed which meets these criteria, pH readings from each lot produced must be taken to assure that the product pH continues to develop normally. It is important that all pH readings are recorded before the product surface temperature reached 110°F and/or before the degree/hour limitations have been reached. If the pH has not reached 5.3 by the time the limitations are met, samples should be taken from the fermentation room before the temperature is advanced. It is recommended that one sample be obtained from each mixer/batch of product.

V. JERKY

A. Definitions

1. "Jerky" means a product made from animal flesh that has been cut into long slices or strips and dried.
2. "Formed Jerky" means a product made from animal flesh that has been shredded or ground and molded into its final shape before drying, which may or may not contain extenders.
3. "Extenders" are any materials, such as textured soy protein or cereals, that are added to the ground or shredded animal flesh and must be properly declared in the labeling of the product.
4. "Marinate" means to soak meat in a sauce to enrich its flavor, to tenderize, or enhance its shelf life
5. "Species Name" jerky shall be manufactured solely from the flesh of the named animal species; otherwise, "Species Name Flavored" jerky shall be the product label.

B. Processing Methods

1. If the same rooms and equipment are used for preparation and packaging, all process ware and food contact surfaces used for slicing of meat and poultry and placing in drying room or dehydrators shall be cleaned and sanitized before any finished product is packaged.
2. The establishment shall facilitate the inspection and monitoring of the treatment process by providing appropriate time and temperature recording equipment.
3. The establishment shall record the time, temperature, and other critical process parameters for each lot of product produced.
4. The establishment shall have, on file on site, a description of the current processing method for each product produced. The processing method description shall include a description of:
 - (a) Handling procedures for meat ingredients, including maximum time and temperature exposures during thawing, trimming, curing, slicing, grinding, shredding, marinating, curing, and any other preparation steps or other applicable product factors;
 - (b) A procedure for identifying a product lot during processing, its lot identification codes, and how the finished product package codes

can be identified with a specific production lot. The establishment shall divide production lots into one day time increments or less;

- (c) Procedures used to comply with the treatment process;
 - (d) The drying procedures and methods used to prevent recontamination of the treated product; and
 - (e) The equipment and procedures used for measuring and recording time and temperature required by the treatment used by the establishment. The measuring devices shall be both readable and accurate within plus or minus 3°F and 1 minute.
5. All product shall receive a lethality treatment that, at a minimum, meets the recommendations contained in the April 2007 USDA-FSIS "Quick Guide on Processing Jerky" and "Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Plants."

Mark Your Calendar

With these important dates:

CASA 6th Annual Educational & Training Seminar

May 9-11, 2012

Pittsburgh, PA

AFDOSS 2012 Spring Conference

May 13-16, 2012

Tampa, FL

AFDO 116th Annual Educational Conference

Hosted by NEFDOA

June 2-6, 2012

Providence, RI

NEFDOA 2013 Conference

May 14-16, 2013

Hampton Beach, NH

AFDO 117th Annual Educational Conference

Hosted by AFDOSS

June 8-12, 2013

Louisville, KY



ASSOCIATION OF FOOD AND DRUG OFFICIALS

2550 KINGSTON ROAD, SUITE 311, YORK, PA 17402

NON-PROFIT ORG
U S POSTAGE
PAID
YORK PA
PERMIT #200