

# Journal of the Association of Food and Drug Officials

Serving the regulatory community since January 1937

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#### From the Executive Director

The significance of an organization might be best understood in its history and traditions. Additionally, we are better able to define our future by recognizing our past and learning from the successes and mistakes that have previously occurred.

One of the true riches of AFDO resides in its history. What began within a few Midwestern states over 114 years ago to improve communication and establish uniformity continues today in the effort to integrate the national food safety system. AFDO's history helps us to better understand current events and how to best respond to them. AFDO celebrates its history at the Burditt Luncheon every year during our Annual Conference where we re-enact AFDO Conferences of the past and remind ourselves of the struggles our predecessors had in their quest to promote uniformity and improve public health. Those fascinating events of yesterday help us understand how we came into existence and how we continue to survive. Isn't it interesting that many of the past battles AFDO participated in are very similar to many we have today, and that the decisions that leaders made before us are a great learning tool we can rely on? AFDO has gone through several organization name changes and periods of uncertainty, but our impact on national issues today is as clear as it was yesterday. We cannot dismiss our history.

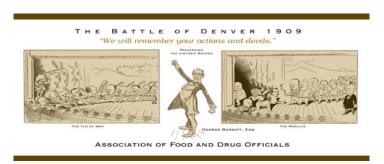
In 1937, AFDO published its first AFDO Journal, which we continued to publish up until 5 years ago. Today, we are very pleased to return to our history and our tradition by once again publishing an AFDO Journal and committing ourselves to do so annually from now on.

I hope you enjoy our reproduction of articles from AFDO's first Journal from 1937 and the selected articles from the past 2 years. The entire AFDO staff is committed to serving our members, and we would very much like to hear from you with your thoughts about our returning to our history and returning to the AFDO Journal.

Please let us know what you think.

Joseph Corby

AFDO Executive Director



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Training Advisor	Dan Sowards
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Association
of
Dairy, Food, and Drug Officials
of
The United States

#### **QUARTERLY BULLETIN**

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J. J. Taylor, Florida Vice-President

Sarah V. Dugan, Kentucky
Walter S. Frisbie, Washington, D. C.
Wember Executive Committee
W. C. Geagley, Michigan
Secretary and Treasurer

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C. S. Ladd, North Dakota

Sarah V. Dugan, Kentucky, Chairman

Editorial Office, State Department of Health, Louisville, Kentucky.

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#### **Announcement**

The Editorial Committee appointed at the Fortieth Conference of the Association presents this bulletin as the first publication of the Quarterly Bulletin of the Association of Dairy Food and Drug Officials of the United States.

In accordance with the action of the Association, realizing the need of a definite and positive program to stimulate interest and to serve the members in a more effective manner than has been the case in the past, the President appointed a permanent Editorial Committee of three members whose duties and responsibilities are to edit and publish all activities of the sectional groups, the annual conference, and information on food and drug law enforcement from states, cities, and counties, which will be appropriate, interesting, and informative to the members.

The first number was delayed until this date owing to the Ohio Valley floods and the postponement of the Executive Committee meeting, and the second will follow shortly.

The Editorial Committee urges that secretaries of local and sectional meetings of food and drug officials forward to the Chairman of the Committee, as soon as possible after a meeting, a report of the conference.

This is the Quarterly Bulletin of the Association replacing the Annual Proceedings and is the responsibility of each member.

# Report of the Proceedings of the Fortieth Annual Conference of the Association of Dairy, Food, and Drug Officials of the United States at Miami, Fla., December 7, 8, 9, 10, 1936

On December seventh, the members of the Conference were welcomed to Miami by Dr. Geo. N. McDonnell, Director of Public Health of the City of Miami, and for the Florida State Department of Agriculture by Mr. J.J. Taylor, State Chemist. Mr. A. M. G. Soule of Maine responded in his usual delightful manner.

Mr. George H. Marsh of Alabama, President, presented his address, urging that greater publicity be given to work of food and drug inspection.

During the following days the program proceeded very smoothly.

Mr. J. Raymond Chittick, in the absence of Dr. T. J. Bryan, gave a charming extemporaneous talk on the history of the Association and the colorful personalities of its early members.

Dr. J. S. Abbott presented a paper on "Butter and Oleomargarine."

Mr. A. L. Sullivan of Maryland read Mr. F. A. Korff's paper on "Suggested Methods of Food Poisoning Investigation and Control."

Cosmetics and their control were discussed in three papers, from the viewpoint of the state health official by Dr. E. W. Campbell of Maine (paper read by Mr. Soule), from the viewpoint of the trade by Mr. H. Gregory Thomas of New York, and from the control angle as provided by the new law in Louisiana by Mr. C. L. Clay (paper read by Mr. Geagley).

Mr. C. S. Trimble, Washington, D. C., presented a fine paper on "Regulatory Problems Relating to the Manufacture of Butter".

Dr. R. F. Cowley, Adviser, National Technical Milk Commission of Cuba, brought greetings from his country and told of the ambitious plans for improvement of the Republic's milk supply.

At the executive sessions, a variety of subjects were discussed.

#### COMMITTEE REPORTS

**Legislative:** Mr. W. S. Frisbie gave a condensed report of the progress and passage of laws relating to food and drugs in Congress and the state law enacting bodies in the year 1936. The report was ordered published in the bulletin.

**Committee on Model Law:** A model State food, drug, and cosmetic law in tentative form was submitted with a sane report. The committee's report was adopted. Copies of the tentative draft and report of this committee may be obtained from the Secretary of the Association.

**Committee on Food Standards:** The report of this committee is printed in full in this number of the bulletin. It was adopted.

Executive Committee: A report was made of the meeting of this committee in Chicago in January, 1936, at which time the program of the conference was planned. Action of the Executive Committee included a plan to publish the 1933-34-35 proceedings in condensed form, the formation of a permanent Editorial Committee for editing the proceedings and preparing news items for the Food and Drug Review, and a request of the Office of Co-operation to prepare a schedule for study by the Association of educational and other qualifications for scientific personnel of food and drug departments

**Editorial Committee:** Report was made of the condensing of the 1933 and 1935 proceedings and of publication of news items monthly in the Food and Drug Review.

**Special Committee:** (Appointed by the President to inaugurate a definite, positive program to serve the membership.) The report of this committee included a plan for publication of a quarterly bulletin with discontinuance of the publication of annual proceedings. The quarterly bulletin was to be sent to the active membership and to selected list of officials not now active members of the Association. The committee reported that for 1936 the dues should be \$10.00 per year as heretofore, and that in future years the dues should be reduced when the cost of publication of the bulletin is determined. After much discussion the report of the committee was approved.

**Resolutions Committee:** The report was approved in its entirety and is published in full in this bulletin.

**Nominating Committee:** The nominating committee made the following report:

Mr. Harry Klueter, Wisconsin, for President

Mr. J. J. Taylor, Florida, for Vice-President

Mr. W. G. Geagley, Michigan, Secretary-Treasurer

Mrs. F. C. Dugan, Kentucky, Member of Executive Committee

The committee report was approved and the candidates named were elected unanimously.

The conference adjourned on December tenth.

#### **EXECUTIVE COMMITTEE MEETING**

Immediately following adjournment, President Klueter called a meeting of the Executive Committee, and a meeting of the committee for formulation of the 1937 program was set for February 1, 2, at Indianapolis. Owing to the Ohio Valley flood of January and February, the meeting was postponed until March 29, 30, at Indianapolis.

The full Executive Committee met and prepared a fine program for the 1937 meeting.

The meeting place selected is Washington, D. C., the Raleigh Hotel, the dates October 26, 27, 28, and 29, 1937.

#### REPORT OF STANDARDS COMMITTEE

One meeting of the Federal Food Standards Committee was held during the week of September 28, 1936. At this meeting the following definitions for egg products were approved.

- 1. LIQUID EGGS, MIXED EGGS. The product obtained by separating the edible portion of eggs from the shells. It is an intimate mixture of the whites and yolks in their natural proportions.
- 2. FROZEN EGGS. The solidified product obtained by quickly and completely freezing liquid eggs.
- 3. FRIED EGGS. The product obtained by evaporating the water from liquid eggs. It contains not more than 7 per cent of moisture.

- 4. EGG YOLK. The product obtained by removing the whites from the yolks in the commercial process of egg-breaking. It contains not more than 12 per cent by weight of adhering white.
- 5. FROZEN EGG YOLK. The solidified product obtained by quickly and completely freezing egg yolk.
- 6. DRIED EGG YOLK. The product obtained by evaporating the water from egg yolk. It contains not more than 5 per cent of moisture.

Proposed and revised definitions were adopted for the following products:

ORANGEADE. The beverage consisting of orange juice, sugar, and water. It contains not less than 25 per cent of orange juice. The acidity may be increased by the addition of lemon juice.

LIME RICKEY. The beverage consisting of lime juice, sugar, and carbonated water. It contains not less than 7 per cent of lime juice.

MOLASSES. The product which remains after separating sugar from the clarified and concentrated juice of the sugar-cane. It may be "light" or "dark". It contains not more than 25 per cent of moisture and not less than 55 per cent of total sugars (sucrose plus reducing sugars). Reducing sugars are calculated as invert sugar.

Light Molasses is molasses which contains not less than 62 per cent of total sugars.

Dark Molasses is molasses which contains not less than 55 per cent of total sugars.

CREAM CHEESE. The soft, uncured cheese made from curd obtained by the action of either lactic fermentation or rennet, or both, on milk enriched with cream. The curd, heated or unheated, salted or unsalted, is drained by gravity and light pressure. The finished product contains not more than 52 per cent of water and, in the water-free substance, not less than 65 per cent of milk fat.

The committee reviewed requests for the consideration of definitions for a number of other products but these definitions were given only brief consideration due to lack of time and were deferred for future action.

At a meeting of the Association Committee held on December 10, 1936, the following members were present:

Harry Klueter of Wisconsin, Chairman George H. Marsh of Alabama J. J. Taylor of Florida

The necessity for additional food and drug standards was quite thoroughly considered. We are in accord with such of the definitions and standards as are set forth in S.R.A., F.D. No. 2, Rev. 4, as do not need revision. We urge early consideration be given to the matter of revision and promulgation of additional standards by the Federal Standards Committee.

We propose at this time the adoption as provisional of the present definition and standards for milks, cream, skim milks, butterfat, and butter; grain products, other than breads; condiments, other than wines and vinegars; edible vegetable oils and fats; tea, coffee, and cocoa products; carbonated beverage and beverage flavors and the proposed definitions and standards for orangeade and lime rickey.

We propose for your consideration a change in the definition of cream cheese so as to read, "A product made from cream or cream and milk".

We propose the fixing minimum moisture requirements for Brick cheese and Emmenthaler (SWISS) cheese.

We propose a study, for the purpose of revision, of existing definitions and standards for breads, pickles, and sausage.

Members of committee:

E. G. Woodward, Connecticut W. R. Plumb, New York J. J. Taylor, Florida Geo. H. Marsh, Alabama Harry Kleuter (Chairman), Wisconsin Milton F. Duffy, California L. E. Walter, Wyoming

This committee report was adopted at the Fortieth Annual Conference, Miami, December 1936.

#### THE REPORT OF THE RESOLUTIONS COMMITTEE

1. WHEREAS: The management of the Miami Biltmore Hotel have so splendidly and generously provided for the accommodation and entertainment of the delegates and their guests at our Fortieth Annual Conference;

THEREFORE BE IT RESOLVED: That this Association extend to the Management and Staff of this Hotel its sincere and whole-hearted thanks for the courtesies extended;

2. WHEREAS: Dr. George N. McDonald has been so untiring in his Committee work and has made such splendid arrangements not only for the business activities of the Association but also for entertainment features;

THEREFORE BE IT RESOLVED: That this Association extend to Dr. G. N. McDonald and his Associates on the Committee and the Staff of his Department its whole-hearted thanks and appreciation for their successful efforts in assuring the success of the Conference.

3. WHEREAS: Mrs. G. N. McDonald so graciously entertained visitors and wives of this delegation;

THEREFORE BE IT RESOLVED: That this Association extend to Mrs. G. N. McDonald its sincere thanks for her hospitality and many courtesies.

4. WHEREAS: Mr. J. J. Taylor and his associates so splendidly entertained the delegates of this Conference;

THEREFORE BE IT RESOLVED: That this Association extend to Mr. Taylor and his associates their sincere thanks and appreciation;

BE IT FURTHER RESOLVED: That this Association extend its thanks and appreciation to the Ft. Pierce Citrus Growers Coop. for their courtesies and spirit of fairness in showing their methods and process used in preparing oranges for the market to the end that Food Officials could obtain first-hand information and better understanding of the processes used and underlying reasons and;

BE IT FURTHER RESOLVED: That this Association extend its thanks and appreciation to all parties concerned for providing transportation, supper, and an exceedingly interesting trip.

5. WHEREAS: The Federal Trade Commission has adopted definitions for preserves, jams, and jellies which conflict with the standards and definitions previously adopted by the United States Department of Agriculture;

THEREFORE BE IT RESOLVED: That this Association go on record as being opposed to conflicting definitions and standards and that we exert our collective and individual energies towards the discouraging of the adoption of standards by the Federal Trade Commission which conflict with definitions and standards previously adopted by the United States Department of Agriculture;

BE IT FURTHER RESOLVED: That the President of this Association appoint a Committee of experienced members to study the report of the Federal Trade Commission on preserves, jams, and jellies for the purpose of making recommendations as to action that should be taken by the Association, in the future, to preserve the fundamental rights of the State and the Federal Food and Drug Administrations to establish standards and to prevent possible conflicting standards and definitions.

#### Committee:

A. M. G. Soule, Chairman, Maine

A. L. Sullivan; Maryland

V. L. Fuqua, Tennessee

This committee report was approved by the Fortieth Annual Conference at Miami, December, 1936.

#### Abstracts of Papers at Miami, December, 1936.

PRESIDENT'S ADDRESS. GEORGE H. MARSH, Supervisor, Division Agricultural Chemistry, Department of Agriculture and Industries, State of Alabama

Adequate tools are necessary for the proper protection of the public in the task of food and drug control. Adequate laws and sufficient funds are essential tools for this work. We must obtain proper state and federal Food, drug, and cosmetic laws, including regulatory laws of advertisement as it relates to these products.

A committee should be appointed to formulate a uniform plan and to direct the procedure for the passage of adequate laws in states and by the Federal congress. The general public has not been adequately informed on the working of either Federal or state food and drug regulatory laws, at least not to the extent of arousing the consumers as they should be aroused as to the value of the protection to them. We should have a well formulated educational feature in our new program.

The work of the sectional groups of food, drug, and health officials should be co-ordinated more closely with that of the national association.

The Association should publish at regular intervals a bulletin for the specific purpose of dissemination of such valuable information as we have.

# BUTTER AND OLEOMARGARINE. J. S. ABBOTT, Secretary of the Institute of Margarine Manufacturers

More than half the people in the world do not eat either butter or margarine. Olive oil, rancid milk fat, vegetable oils, and fats of many other types used singly or in admixture, provide the fatty constituents of the diet.

The principal butter and margarine eating countries are the northern European countries, the United States of America, and Australia.

In the manufacture of margarine, purified fats and oils that are neutral or practically neutral in taste are flavored with ripened milk. Milk is the source of the flavors and aromas of margarine as well as of butter.

The wholesomeness and food value of margarine is vouched for by all scientific authority. The digestibility and energy value (calories) of margarine and butter are practically the same.

Protest is made against special taxation on margarine, as it is believed that the consumer has an inalienable right to purchase the articles of food of his choice on the most economical basis.

# REGULATORY PROBLEMS RELATING TO THE MANUFACTURE OF BUTTER. CHAS. S. TRIMBLE, Bureau of Dairy Industry, United States Department of Agriculture, Washington, D. C.

(Published in full in the January 13, 1937, issue of "American Creamery & Poultry Produce Review," and in the March, 1937, issue of "The Milk Inspector.")

Recent activity for quality improvement of dairy products has been timely and results have been accomplished, but enforcement of certain laws, rules, and regulations is not a real attainment unless enforced by combined efforts

of all regulatory agencies to an extent that a cleaner, safer, and more healthful product reaches the consumer.

There are several Federal agencies concerned with the enforcement of butter laws. The activities of the Food and Drug Administration are well known. The Bureau of Dairy Industry controls process or renovated butter and plants and inspects dairy products for export. The Bureau of Internal Revenue of the Treasury Department administers the adulterated butter law of May 9, 1902. State or local officials finding adulterated butter sold would do well to get in touch with a revenue agent as conviction under the revenue law means penalties up to several thousand dollars and has a convincing and far-reaching effect.

In spite of state laws and standards for butter as well as sanitation requirements for establishments, cream testing and pasteurizing, with also grading laws in several states there is still a large volume of farm-made butter to which regulation or inspection has not reached out though churned raw from sour cream and often handled in a careless and unsanitary manner. In the South farm-made butter is sold in all city markets and in 1934 twenty-three states produced more farm-made butter than creamery butter. Much of this butter is unmarked as to weight and name of producer and questionable as to manufacturing methods, health, both of cows and people, as well as the legality of the finished butter.

Packing-stock butter (a large baking company in the South is reported buying 75,000 to 100,000 pounds unrenovated packing-stock yearly for use in its baking products), ladle butter, so-called cooking butter, and other less known grades of butter afford fields for regulatory officials to investigate.

A comparison of milk inspection practices with butter manufacture control shows milk subject to more regulation and inspection than any other food in order to insure the consumer of milk, a clean, safe quality product. Butter, a product of milk -- a highly perishable and universal food -- should be carefully guarded throughout its production background on the farm and progress elsewhere to the consumer but has not been made subject to any of the regulations or inspections that apply to milk. While buyers persist in buying bad cream educational work among producers will not remedy the situation.

Grade A and Grade B milk has been accomplished in many areas but not without opposition and establishment of grades for butter would mean more both to the industry and consumer than false, misleading, or will-o'-the-wisp slogans and statements.

Butter is defined by law as being made exclusively from milk and cream and from a practical and control angle must be determined how exclusively and what should be the age and character of the milk or cream used. Decomposition or deterioration as shown by proteolysis begins when 0.2 to 0.3% acid develops in cream and continues with increase of acidity. Yet cream that contains from 0.8 to 1.0% acid and even higher is used for making butter at the present time. Much cream that is not edible as cream has been used and is being used for making butter. Should such cream be permitted to be made into butter? The 4-day plan was in use as far back as 1931 and does not appear to be a solution. Processing of cream for butter making is not objectionable if it makes a safer, cleaner product; but its use merely to cover up or remove visible evidence of contamination without serious effort to eradicate the source of contamination should make it the concern of control agencies and force them to look into these methods. Methods of filtration to remove visible and insoluble filth still leave the soluble material in such filtered cream.

The partial neutralization of the acid of sour cream is accepted practice, but the use of stronger than accepted neutralizers especially in combination with agents possessing other properties (i.e., deodorizing) to enable use of cream which could not otherwise be made into saleable butter raises a question of control. There is no question as to the obvious duty of regulatory agencies in the case of old, dented, cracked, and otherwise unfit cans for delivery of cream and they should be prohibited by regulations stringently enforced.

# COSMETICS AND THE NEED FOR CONTROL. ELMER W. CAMPBELL, D.P.H., Director Division of Sanitary Engineering, Maine Bureau of Health

Cosmetics are defined by one of the bills introduced in Congress, as follows: "All substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of the person."

Cosmetics have been used throughout the history of mankind, although until recently their use has been limited. During the past twenty years the cosmetics industry has grown from a very small industry to one of the five largest, all without any regulation by law.

The majority of present-day cosmetics are made by ethical manufacturers and are harmless. However, some manufacturers, either willfully or through ignorance, market cosmetics containing harmful substances and may not be found out until a great deal of damage has been done. It is the latter type that makes regulation by law necessary.

Maine and Louisiana now have state laws regulating the sale and use of cosmetics. Since the Maine cosmetic law has been in effect, analyses have been made of about seven thousand preparations. In these no less than twenty-one different, harmful substances have been found in 543 cases. These harmful substances might be classed as follows: (1) Dangerous metallic poisons; (2) Violent caustic and irritant substances; (3) Substances violently irritating to allergic persons; (4) Substances more or less irritating or poisonous which should not be present in excess of definite tolerances and the manner of use indicated to adequately safeguard their use.

Metallic poisons should not be used in cosmetics because the frequent and repeated applications may possibly cause chronic poisoning.

It is recognized that "some persons are particularly susceptible due to idiosyncrasy to certain classes of substances which are capable of causing severe injury to such individuals. The worst offenders amongst these substances are the aniline derivative dyes which are widely used in hair dyes, shampoo tints, and similar preparations...none of these should be sold excepting when they bear full and complete instructions for testing the individual and determining whether or not they react to these particular substances, and should under no condition be used until after these tests have been made."

Investigations need to be undertaken to determine tolerances for a number of more or less poisonous metals and irritating organic compounds.

# CONTROL OF COSMETICS FROM THE TRADE VIEWPOINT. H. GREGORY THOMAS, Director, Board of Standards, Toilet Goods Industry

The cosmetic industry should be considered as a basic industry, which is destined to become permanent and important in American life, and in which the leading manufacturers have a background of experience, capital, and scientific control.

It is urged that the cost of cosmetics be severed from questions involving public health, that is, the possible injuriousness, adulterations, or misbranding of cosmetics.

It is believed that if the cosmetic industry was controlled from the inside, by its own members, there would be less need of governmental restrictions on cosmetics.

In order to prevent the use of new and untried ingredients or raw material which may prove harmful, the Toilet Goods Association in May, 1936, proposed a Bureau of Standards within their own organization, such a Bureau to exercise a scientific control over the raw materials of the industry, and to supervise the advertising and labeling of all cosmetic manufacturers, who would voluntarily submit their business to such control.

Trade supervision of the sale of cosmetics, with ample authority for removal from commercial channels by State or Federal authorities of dangerous products, is urged as the sanest method of control.

# LEAD AS A CONTAMINANT IN MAPLE SYRUP. C. P. MOAT, Chemist of the Vermont State Department of Health

On May 18, 1936, the U. S. Food and Drug Administration notified the Vermont Department of Agriculture and the Vermont Department of Public Health that samples of Vermont maple sugar and syrup have been found to contain certain quantities of lead. This has formerly been known to be present in very minute amounts, but recent improvements in analysis indicate that more lead exists than was previously suspected. New York State and Canadian products are also involved.

In consequence of this finding a ruling has been made that beginning January 1, 1937, any maple product found to contain lead will be classed as adulterated and its sale within or without the state will not be permitted. The importance of this ruling to the maple industry cannot be too strongly emphasized.

#### **How Lead Gets Into Maple Products**

Extensive inquiry has been carried on for several months by the State Departments assisted by private concerns dealing in maple products, and the conclusion has been reached that lead finds its way into maple from two or three sources:

- 1. The use of lead paint in painting sap buckets and other utensils.
- 2. The use of "terne plate" for the manufacture of sap buckets, spouts, evaporators, and pipe lines. "Terne plate" is an alloy which contains from 50% to 70% lead in its composition. It has been used to some extent for making buckets, spouts, and pipe lines and occasionally for making evaporators.

3. Lead may also enter the product from the use of utensils or containers which have been manufactured or repaired with solder on the inside.

Maple sap or syrup standing in these utensils or containers is found to absorb enough lead to give distinct tests when the product is analyzed in the laboratory. Sap which has become sour or fermented is especially active in taking up lead.

#### **How to Prevent Lead in Maple Products**

From the first, it was decided that it would be impracticable to require sugar makers to discard their present equipment. Therefore research has been carried on to discover some way to safeguard producers against this menace to the industry. As a result of this research, in which expert chemists of the industry have gladly co-operated, the following warnings are issued.

- 1. Do not use white lead or any lead paint for the preservation or protection of any maple utensils.
- 2. Collect and boil sap as rapidly as possible so that it will not start to ferment or sour. On a warm day even a few hours delay will show a change in the sap.
- 3. Replace as rapidly as possible any equipment made of terne plate. Until such replacement can be made, they must be resurfaced as suggested below.
- 4. For the initial painting of buckets and other equipment and for covering of lead paint heretofore applied, a paint which is free from lead and other poisonous substances should be used.

#### **NOTICE**

The Secretary calls attention to the action of the Association that the dues for 1936 are ten dollars (\$10.00) and were due at the annual conference. He plans to send bills for the 1936 dues to all members shortly.

#### **About the Authors**

Jeff Farrar, D.V.M., Ph.D., M.P.H., is the Associate Commissioner for Food Protection in the U.S. Food and Drug Administration where he oversees and coordinates various efforts in the Office of Foods. Dr. Farrar was previously the Branch Chief of the Food and Drug Branch in the California Department of Public Health where he led a large, diverse state food, drug, and medical device regulatory program. graduated from the University of Tennessee College Of Veterinary Medicine in 1981 and received his Master of Public Health degree from the University of Minnesota in 1983 and his Ph.D. in epidemiology from the University of California-Davis in 1998. Dr. Farrar completed the Centers for Disease Control and Prevention's Epidemic Intelligence Service two-year training program in 1985. Dr. Farrar lead numerous environmental investigations of foodborne outbreaks in California including salmonellosis associated with eggs, sprouts, and cantaloupe, E.coli O157 illnesses from leafy greens, unpasteurized apple juice and sprouts, and cyclosporiasis from berries. He has worked closely with numerous industries and agencies to develop preventive guidelines for safe food production and has co-authored numerous scientific publications.

Ron Klein is the Program Manager for the Alaska Department of Environmental Conservation's (ADEC) Food Safety and Sanitation Program and Acting Chief of the Alaska State Environmental Health Laboratory. He has been with the department since 1987 and has managed a number of the department's environmental programs including Contaminated Sites, Air and Water Data and Monitoring, Water Quality Assessment and Monitoring, and Water Non-point Source Pollution Control.

Ron is President of the Association of Food and Drug Officials (AFDO) and has served on the Board of Directors of AFDO since 2006 and participated in the development of the International Food Protection Training Institute. He served on the Board of Directors for the Western Association of Food and Drug Officials from 2006 - 2008. He Co-Chaired the AFDO Retail Food Committee and coordinated the update of the AFDO Food Code Pocket Guide to include the 2005 Model Food Code. He chaired the AFDO Manufactured Food Regulatory Program Standards (MFRPS) Workgroup which provided FDA with recommended changes to the MFRPS and is participating in the FDA MFRPS Committee which replaced it. He is also serving on FDA's National Standards Task Group. Ron has served as Co-Chair of the Conference for Food Protection's (CFP) Program Standards Committee; served with the CFP Certification of Food Safety Regulation Professionals workgroup; and was a member of Council II during the 2010 Biennial Conference.

Ron was on the Board of Directors of Alaska Quality Seafood which provided third party audits for Alaskan seafood processors and buyers and has served in leadership roles for a number of local, regional and national associations responsible for environmental issues including the Western Governor's Association and the Association of State and Territorial Waste Management Officials.

He has an M.S. in Environmental Quality Science from the University of Alaska, an M.S. in Forest Resources from the University of Washington and a B.S. in Environmental Studies from the University of Oregon.

**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.

#### 2009 Glenn W. Kilpatrick Address, Michael R. Taylor

#### Michael R. Taylor Research Professor School of Public Health and Health Services The George Washington University

#### AFDO 113<sup>th</sup> Annual Educational Conference Chicago, IL -- June 7, 2009

Thank you for having me here today. And thank you for the honor of delivering the Glenn W. Kilpatrick Memorial Address.

Let me also say, right up front, how pleased I am to be part of this AFDO meeting. AFDO has been around for a long time - 113 years to be exact - and has been a key part of the network of people and organizations that make the food and drug community a community. It feels good to be a part of it.

And, having known AFDO since the 1970's, for some of those years as a food and drug official myself, it has been a great pleasure for me to collaborate very recently with AFDO in my food safety work at the GW School of Public Health and to work with wonderful AFDO people, like Joe Corby, Jerry Wojtala, Joe Reardon, Jim Austin and many others. I thank them for being great partners.

Now, I'm sure many of you – or at least many of the long-time AFDO veterans in this audience – knew Glenn Kilpatrick. I didn't know him, but in the course of preparing this address, I learned some things about him.

One of the things I learned is that Mr. Kilpatrick and I actually overlapped in our tenures at FDA, late in his career and early in mine. In the late 1970's, he of course was the prominent, long-time leader of federal-state relations at FDA, pursuing his big picture vision of partnership among federal, state and local officials to protect public health.

I, on the other hand, was a novice staff lawyer prosecuting dirty warehouse cases and reviewing GRAS affirmation Federal Register notices for what was then FDA's Bureau of Foods.

Needless to say, with him way up there and me way down in the trenches, our paths would not normally cross.

But, in preparing for today, I learned more about Glenn Kilpatrick than the biographical facts. I learned about the content of his vision for how FDA and the states could work together for the good of American consumers. And I learned about some of the things he did to turn vision into reality.

And it's here – on the ground of vision *and* action to build the federal-state-local partnership – that I think all of our paths cross with Glenn Kilpatrick's.

Glenn knew first and foremost that the public expects a lot from food and drug officials. And he knew that, in our unique federal system, federal, state and local officials would all be stronger in meeting the public's expectations if they worked in true partnership.

So, in 1960, after seven years running the state food and drug program in Utah, Glenn brought his state experience and his vision for the national food and drug regulatory system to the FDA, and to the newly formed Division of Federal-State Relations. And, there, he made his presence felt.

At FDA, Glenn lived his vision of real partnership, in part, by always being the one around the FDA table to say "What about the States"? Enthusiastically, persistently, I'm told, always driving home the point that states were vital and valued partners for FDA in just about every aspect of its work.

Glenn did this because, from his experience in Utah food and as President of the Western Association of Food and Drug Officials, he knew first hand that, on food safety in particular, the work of the states and localities is not merely complementary to the federal role, it is foundational.

After all, as this audience certainly knows, state and local agencies do most of the food inspections; test most of the food samples; and bring most of the food-related enforcement cases.

Glenn brought his knowledge and his vision into FDA's deliberations, but he didn't live out the vision just by talking. He acted.

He worked to establish rapid communications among FDA's headquarters and field offices and their State counterparts, as well as joint planning conferences with state officials.

He stepped up the commissioning of state officials to act in full concert with FDA. And he pioneered the FDA program of contracting with state agencies to conduct inspections on FDA's behalf.

And, so, Glenn Kilpatrick laid the foundation for a future food safety system based on genuine partnership, seamless communication and joint action to protect consumers.

And look how far we've come. Using today's modern information and communications technologies, we've moved from telephone trees and fax machines to PulseNet, FoodNet, and eLexNet. These innovative public health information systems involve the federal government but are rooted in the work of state and local officials, who use them to collect and share data of great national importance.

Beyond data systems, we have the longstanding federal-state cooperative programs for milk and shellfish; we have multiple editions of FDA's widely adopted Food Code for retail food safety; and we have FDA's retail and manufactured food regulatory program standards, a collaborative initiative to elevate state and local implementation of food safety programs and ensure strong enforcement of food safety standards. And, of course, FDA depends on states for the conduct of the majority of FDA's food safety inspections.

These are achievements of which Glenn Kilpatrick would, I'm sure, be justly proud, as should be all who have worked to bring them about.

But, where do we go from here? We've come a long way in building the federal-state-local partnership on food safety, but, as I'm sure everyone in this room would agree, there is more, much more, to do.

The fact is that constant change in the food system constantly changes the nature of the food safety job.

New food production, processing and retailing techniques bring economy and convenience but also new risks.

Globalization of the food system expands choice and reduces costs but floods the market with foods and ingredients whose production is largely hidden from view.

And foodborne illness remains an important public health and societal problem in the United States, due both to familiar hazards, like chemical contaminants and Salmonella, and to emerging new hazards, like E. coli O157:H7, which were not even on the radar screen when Glenn Kilpatrick worked at FDA.

And, so, there is much more to do to protect consumers and to build the federal-state-local partnership that is essential to success, which is something AFDO has known and been saying for a long time. Back in the late 90's, in conjunction with the Clinton Administration's National Food Safety Initiative, AFDO embraced the vision of an integrated national food safety system, and has since advocated for it and worked hard to achieve it.

I've had the good fortune to work recently with AFDO on projects that relate directly to implementing the vision of a national integrated food safety system. These projects have candidly assessed where we are now and where we need to go to fulfill the vision. And we've learned some important things.

We've learned that there is much more we can do to coordinate and integrate how food safety information is collected and shared among public agencies, whether it's inspection observations, lab test results, or epidemiological data on foodborne illness.

This is critical because preventing foodborne illness is fundamentally a knowledge enterprise, and we need to be sure we both collect the right information and make the best use of what we have, as real partners in an integrated food safety system.

We've learned, however, through dialogue among stakeholders across the food safety system, of the many barriers to the sound collection and seamless sharing of important food safety data. There are legal, policy, and technical barriers. There are bureaucratic and cultural barriers. And there are funding and capacity barriers.

Likewise, while the food safety system is getting better all the time at detecting and responding to outbreaks of foodborne illness, we've learned there is room for improvement in how epidemiologists, environmental health specialists, and regulators work together to ensure both timely detection and containment of outbreaks.

It's partly a matter of improving the information flow, but it also involves standardizing data collection practices, clarifying roles, and investing in the capacity nationwide to respond with the greater timeliness and accuracy we know is possible.

Finally, we've seen the opportunity – and the need – to better integrate federal and state inspection and compliance activities and thereby better prevent foodborne illness.

Prevention is, of course, the fundamental public health goal of the food safety system.

We know that many actors in both industry and government – and consumers as well – play critical roles in preventing foodborne illness, with the government's unique and essential role being to set and enforce sound, prevention-oriented food safety standards.

And government will be successful in its role only if all elements of the government system – federal, state and local – are working in concert and from the same play book in terms of such fundamentals as information systems, test methods, training, and inspection strategies.

To me, one of the really striking things about the history of our food safety efforts and the federal-state-local collaboration is that the progress we have made to date has largely been the product of conscientious people working hard to do the right thing, typically without any high-level political mandate and always without significant resources being dedicated to building an integrated system.

Now, there is every reason to believe that this will change. The food safety events of the last few years have caused a political sea change, which includes the recognition that Congress must modernize the legislative mandate for the federal food safety system.

The political sea change also includes the recognition that a modern, preventive food safety system has to be a real *system* – one that takes full advantage of capacities and programs at all levels of government, that builds those capacities, and that integrates their prevention and response efforts through real partnership.

Congress is actively considering bills that would provide FDA with a modern food safety mandate and make building an integrated national food safety system a matter of national policy. And there's good reason to believe such legislation will pass this year.

If it does, that will be a transformative moment in the history of food safety in the United States. FDA would have a clear mandate and a new accountability to build the integrated system that AFDO has been calling for and that many individuals, like Glenn Kilpatrick, have been working on.

But that moment – the passage of legislation – is only a moment if it is not followed by the hard work of implementation. And that will depend again on the people in this room and people working throughout the food safety system.

But let's not underestimate the difficulty of the task. The change envisioned by the pending legislation is fundamental. It involves changing not only laws and policies but longstanding practices, and it requires building new working relationships across organizational lines that sometimes make working together hard, even when the intentions on all sides are good.

I have absolutely no doubt, however, that the people working in the food safety system are up to the challenge that is coming. Glenn Kilpatrick was special. But, with no disrespect to him, the system is full of Glenn Kilpatricks.

It's full of people who are committed to act and to fulfilling the vision of a food safety system that successfully prevents foodborne illness, and that thus gives American consumers the protection and peace of mind they so strongly desire.

Thank you, again, for the privilege of being here.

#### 2010 Glenn W. Kilpatrick Address, Jeff Farrar

# Jeff Farrar, DVM, MPH, PhD Associate Commissioner for Food Protection U.S. Food and Drug Administration

#### AFDO 114<sup>th</sup> Annual Educational Conference Norfolk, VA -- June 20, 2010

Thank you, AFDO Board, for the invitation to give the Kilpatrick Address. What an incredible honor to give this talk. It is the hardest one of my life for several reasons.

First, I have heard many of these talks given by individuals who I hold in extremely high esteem. Those selected to give the Kilpatrick Address are individuals who are deeply committed individuals who have invested decades of work in this field. I don't harbor any illusion that my accomplishments fall into the same category as a Joe Corby or a Rick Silverman. So, it is an incredible honor to be selected for this talk.

Second, this is the 30<sup>th</sup> anniversary of the establishment of the Glenn W. Kilpatrick Memorial Address, passed by a vote of the AFDO Board of Directors in Bismarck, North Dakota, in 1980. This lecture was initiated to highlight the efforts of Mr. Kilpatrick in his state and federal service in federal state integration, establishing planning conferences between FDA and states, in intensifying the commissioning of state officials, and helping establish contracts with states for inspections. Glenn Kilpatrick's efforts more than 30 years ago, still serve as a model for us today. I hope he would be pleased with our recent efforts.

Third, although I have heard quite a few Kilpatrick presentations in the past, I was not sure what the specific parameters were for the presentation. I sought some advice from several individuals in AFDO who have given this talk and who have listened to dozens of others over the years. Their guidance was helpful, and I think very appropriate. Being a trained epidemiologist, I noticed there was a pattern to their feedback. See if you can spot the pattern here. The three most important points, they said, were:

- 1. Don't talk too long as AFDO folks want to eat, socialize, have a beverage, and perhaps talk about FDA a bit.
- 2. Talk about something that is important to you, something you believe or feel strongly about.
- 3. Don't talk too long as AFDO folks want to eat, socialize, have a beverage, and perhaps talk about FDA a bit.

So let me tell you what I feel strongly about so we can get on to 1 and 3.

<u>First, these are difficult times for state and local food programs</u>. The negative news often outweighs the positive with layoffs, budget reductions, eroding programs and morale; new administrations and managers who don't understand the critical nature of our programs and our achievements; and state and local legislators who want to do something but may not be quite sure of what the best fixes are. For example, they might hold hearings one week for improvements in produce safety and hearings another week for decreases in the regulatory oversight of raw milk.

- To be frank, there were several reasons why I decided to leave a 12-year career with the state where, with excellent program managers (such as Inge Small and Pat Kennelly here tonight), scientists, and staff, we built a very solid food, drug, and medical device program with some innovative approaches. One of the reasons was the lack of recognition within the state of the critical importance of food safety regulatory programs at the state level. Our program often seemed to be a bit of an "odd duck" in that we were one of the few regulatory programs in a very large state health department, and we received high level attention only when there was an outbreak or other similar event. Getting new ideas implemented, even those that did not cost much, if anything, seemed to be extremely difficult, if not impossible. Leaving a 12-year career with excellent staff and moving my family across the country was no small decision.
- I believe that we (collectively) have to take some blame for not doing a very good job of telling our food safety story, communicating the accomplishments and the dangers associated with ongoing budget and resource cuts at the state and local level. We have an incredible story to tell, and if told correctly and by enough of our groups and associations, will result in widespread support for improvements in food safety programs. The story of food safety, and food safety needs, especially at the local and state level, is a very compelling one. It is a story, if told in the right way, that will generate wide spread support.

However, I believe we have yet to tell this story in a compelling and coordinated way that links Health Officers, Environmental Health Directors, Food Program Managers, and Food Safety Laboratories with consumers.

Second, yes, there are problems, but I believe that, after many years of effort, we are making significant and real progress toward a truly integrated food safety system. I was present at the first FDA-50 state meeting over 10 years ago to try and launch an integrated food safety system. Although much time and effort was put forth at that point, the effort was not sustainable. However, forces are coming together now to move our cause of integrating federal, state and local government resources further:

- The issue for FDA is no longer one of "if this is the right path", it is one of how quickly can we get there, how we can ensure that we have the appropriate infrastructure to support this effort long term, and what resources can be brought to bear.
  - For example, I believe that funding pilot programs such as the 9 rapid response teams (RRT's) is a very good example of the direction we are taking. Pilot programs such as these are needed to test and fine tune new ideas. However, these programs cannot be successful in the long run if there is inadequate infrastructure within FDA, without care and feeding through guidance and clear expectations, and without clearly identifying what the next steps are to advance and evolve this from an initial and important "let's try some different approaches and see what works" phase. Through the leadership of states and DFSR, that effort is getting back on track. However, we have to think beyond funding 9 states or 29 states to a broader discussion of what our needs are collectively in investigating outbreaks and what is the most effective approach and how can this effort be sustained? We have to ask other questions, such as how can we link our efforts on the Environmental Investigation side with similar efforts on the Epidemiological side from CDC re: outbreak sentinel sites? Operating as silos does not get us to an integrated system.

- Another reason we are making real progress is support within the administration to make it happen. In speaking with the Commissioner and now Deputy Commissioner before I accepted the job, it was clear that there was very high level support for improving the system, developing an integrated system and much more in FDA. Part of the attraction of working at FDA was the opportunity to do many of the things Glenn Kilpatrick is recognized for. I can say that in my 7 months at FDA, my thoughts about FDA from the outside have been confirmed on the inside. FDA is a very large bureaucracy and things occasionally are difficult to move quickly (personnel and IT being two at the top of the list that you might identify with). However, FDA is very similar to state and local food safety agencies. There are an incredible number of very dedicated, hard working, very knowledgeable individuals who want to improve the food safety system.
  - In addition, public support for these changes is increasing. On June 8, the Institute of Medicine released its report "Enhancing Food Safety: The Role of the Food and Drug Administration." A major recommendation was that we have to do much more to fully integrate our activities. The IOM said that integration will require harmonization so that all programs and functions related to food safety meet a minimum set of standards. Further, IOM said that FDA has standards in place that, if broadened and implemented properly, could serve as a basis for this harmonization. This finding reinforces the importance of the MFPS and RFPS programs for us all. If we cannot demonstrate that we have consistently applied, science based standards for state and local programs, then we will not have an integrated food safety system. These programs are not, in any way, intended to signal that states or locals "don't know how to do it" and FDA does. These efforts are designed to improve all of our programs. State and local input into and updates of these standards remains a critical component to their success.
  - Congress also supports these changes. Pending food safety legislation in Congress would mandate expanding partnerships and building an integrated national food safety system. For example, provisions exist in various versions of the bills that address training for state, territorial and tribal officials. Provisions also exist on the need to coordinate surveillance systems and share findings among us. We don't know what the final legislation would contain, but it is clear that an integrated system is a key theme.

- Third, I believe that the only way we will succeed in achieving this integrated system is working closely with AFDO and other associations and truly listen to each other. There are many good ideas that can be implemented. Ideas such as an annual or bi-annual manufactured food conference, similar to the retail focused Conference for Food Protection, are simply very good ideas, make sense, and should be explored further. A Produce Safety Alliance, similar to the very successful Seafood Safety Alliance, is another very good idea. Good ideas, however, do not automatically happen, nor do they mean the final product will look exactly the same as the initial idea. We must continue the dialogue to figure out which good ideas will be implemented first.
- Fourth, I believe that our current approach to inspections will have to be modernized far beyond categorizing firms and sharing inventories. These are important steps, but we must find ways to fundamentally reinvent how we identify and prioritize risks, how we focus our resources on the highest risks, and how we achieve compliance by utilizing all the untapped information; information from associations, from private third party audits, from other federal and state agencies to ensure compliance. As part of this new inspection and compliance system, we must use a variety of tools and approaches to achieve compliance. Our technology must evolve to allow us to obtain and mine data from numerous sources for targeting firms for inspections, including international data. Where science/data supports it, we should conduct different types of inspections in different risk situations, including abbreviated or targeted inspections looking at the critical points in the prevention-based food safety plan. In addition, we must input and manage data in real time.
- Fifth, I believe that we, collectively, have to <u>carefully assess and identify real public health-based metrics</u> to demonstrate the positive impact of an integrated, prevention-based food safety regulatory system. Process based metrics such as counting the number of inspections are important to some but are not the best measures of the effectiveness of our programs and can divert us from our real task.

Sixth, I believe that outbreaks indicate failures of the food safety system and as unfortunate as each illness and outbreak is, these <u>outbreaks represent significant learning opportunities for us to use in a prevention based food safety system</u>. We cannot succeed in this learning effort unless we dedicate a sufficient number of full-time resources to become experts in all phases of foodborne outbreaks from planning to training, to response to documentation and to implementation of lessons learned in a prevention-based system. Outbreak investigations cannot be a part time job. FDA is re-examining how we manage outbreaks and we will need your input and involvement. Our goal is to minimize the number of outbreaks and illnesses and when they do occur, investigate promptly and thoroughly and use the findings to drive improved preventive measures.

Recently, Commissioner Hamburg directed the Deputy Commissioner for Foods to immediately begin recruiting for a Chief Medical Officer for Foods and Outbreak Director who will provide direction, leadership and oversight on all phases of foodborne outbreaks. The Commissioner also directed the Deputy Commissioner to assemble a Foodborne Outbreak Team, composed of representatives from ORA, CFSAN, CVM, and OEO who will work under the direction of the CMO/Outbreak Director. This team will be a full-time dedicated group of HQ and field individuals who work solely on outbreaks and food incidents. Your continued input and suggestions will be critical.

Lastly and most importantly, I believe that dedicated individuals such as
those of you here in the room today have had a profound impact in
bringing about improvements in the food safety system within your own
programs and at the national and international level. However, we have
not assembled all the pieces of the puzzle yet. Your continued diligence
and effort and constructive input are very much needed.

In closing, there are no magic bullets coming this year (aside from the possibility of passing pending legislation), no fast fixes, and we simply have to accept that it will likely take time to rebuild what has been lost including resources and morale. However, during this rebuilding, we can and must rebuild with an eye toward new and better ways of doing things that can be sustained over time.

Thanks for your patience and for the honor of presenting this talk. Now, let's go eat, have a beverage, and perhaps talk a little about next steps to achieving an integrated food safety system.

#### 2009 President's Address, Gerald Wojtala

#### Gerald Wojtala President

#### AFDO 113<sup>th</sup> Annual Educational Conference Chicago-Oak Brook, IL -- June 7, 2009

Welcome to the 113th Annual Educational Conference of the Association of Food and Drug Officials. We are all very excited about this year's conference as it promises to be both exciting and informative. I find it amazing that we have met 112 times before today! AFDO has a deep history that can be explored while you are here by talking with many conference veterans and with George Burditt who can tell you everything you need to know about Chicago. An exciting program is planned, with high level guests and speakers, with over 325 attendees, and, most importantly, we have the perfect setting to accomplish the high–level networking that an AFDO conference is noted for.

I have enjoyed my Presidency tremendously! This has been an extremely busy year for AFDO and I would like to share with you some of our association's accomplishments. But first I want to go back to the Kilpatrick Memorial address last year. I made a mental note about a couple of things Rick Silverman shared with us back then. First, Rick talked about serendipity and being in the right place at the right time during his career as a lawyer with FDA. And whether serendipitous or not, this past year, AFDO saw a convergence of issues forming – a "syzygy" of events aligning and portending major change. As I spoke at the Affiliate conferences, I described this syzygy – or as the gentleman from North Carolina, Joe Reardon, calls it "scissor-gy" – as a major opportunity for AFDO to grasp. And grasp it we did as the most sweeping changes to the Food, Drug and Cosmetic Act in decades were introduced in both Houses of Congress. AFDO was instrumental in putting forth the many concepts involved in the creation of a nationally integrated food safety system that found their way into the bills.

The second thing Rick Silverman did was challenge us at AFDO to do things differently – not to remain stagnate – especially when it comes to trying new approaches at the annual conference. I believe we took Rick's words to heart and you will see some noticeable changes in the conference program that we hope will make for some great new traditions.

At the 50-State Meeting called by FDA in St. Louis last August, AFDO's President, President Elect Ron Klein, and Vice President Joe Reardon decided to meet under the Gateway Arch to strategically plan and position AFDO during our coming 3 years. It was a warm, beautiful day on the banks of the Mississippi River and we couldn't help but to think of Mark Twain as we watched the parade of river boats (and helicopters) making their way up and down the wide river. After we identified potential threats and opportunities facing our association, we quickly zeroed in on a number of initiatives and solutions that we grouped under four main goals:

- Impact food safety legislation
- Facilitate food protection training/education
- Establish AFDO as the premier food protection association
- Increase/facilitate communication in the food protection community

I'll share a little about our progress on the goals but want you to know that in preparation for this meeting in Chicago, I found out that Mark Twain was a frequent visitor here. However, I was only able to find two quotes from him about Chicago and I apologize to the Reverend and to Mr. Burditt here with us since both of these quotes have to do with the devil. The first one goes like this:

"Satan (impatiently to newcomer): The trouble with you Chicago people is you think you are the best people down here; whereas you are merely the most numerous."

Now, if you plan to shop at the Miracle Mile while you're in town and try to park on Michigan Avenue, you might experience some sticker shock. And it appears there was no difference in Twain's time. His second quote:

"When you feel like telling a feller to go to the devil, tell him to go to Chicago — it'll answer every purpose and is perhaps a leetle bit more expensive."

Let's now look at some of the events and actions addressing the four main strategic goals.

First: Food Safety Legislation. Now, more than any other time in recent years, the opportunity has presented itself to take major leaps toward building a fully integrated national food safety system; one that was envisioned by then President Dan Smyly over ten years ago. This syzygy – or convergence of issues – has resulted in the movement of the long awaited food safety bills through Congress. Leading up to the introduction of these bills, AFDO was extremely active in setting the stage through work with Mike Taylor on the grant to George Washington University examining the roles that state and local government play in the food safety system and how to leverage the capacity at all levels to integrate the system. A second grant project started this year involves proposing funding mechanisms to support an integrated food safety system. At this time I would like to ask everyone here who has been involved with these grants to please stand.

Past President Steve Steingart started a tradition last year of making visits to Capitol Hill in order to educate folks in Congress about issues important to AFDO. In keeping with that tradition, AFDO visited and responded to numerous members of Congress and their staffs including those of Congresswoman DeLauro, Congressman Schauer, Senator Durbin, Congressman Dingell, Congressman Waxman, Senator Burr, and Senator Stabenow. AFDO also drafted and sent position statements and letters to Congress. You will find those documents in your conference binders.

In anticipation of calls for regulation stemming from produce outbreaks, AFDO led an effort to create a model On-Farm Food Safety Regulation. I would like to recognize Marion Aller from the Florida Department of Agriculture and Consumer Services along with Doug Saunders from the Virginia Department of Agriculture and Consumer Services for their outstanding leadership in chairing the diverse workgroup that produced this model regulation.

In order to address the issue of acceptance of laboratory analyses in support of an integrated system the AFDO Laboratory Committee performed an important survey. Agriculture and public health food labs across the country responded to survey questions about ISO accreditation and standard methods. I would like to ask Dan Rice from the New York Department of Agriculture and Markets along with Yvonne Salfinger from the Florida Department of Agriculture and Consumer Services to stand and be recognized for this accomplishment.

Second: Training and Education. There is much activity on the training front of late. Dr. Steve Otwell from the University of Florida and chair of the Seafood HACCP Alliance has engaged AFDO to reinvigorate Seafood HACCP training. In anticipation of the release of the revised Hazards Guide, Steve has begun the process of preparing and updating trainers by offering Trainthe-Trainer sessions.

AFDO was approached by Dr. Mike Moody last year to provide Subject Matter Experts for the development of a training course. Mike represents the National Center for Biomedical Research and Training at Louisiana State University. The AFDO SMEs have worked diligently since August 2008 to create a Department of Homeland Security certified course called Food Emergencies: Practice and Execution. This course is offered free to any state or jurisdiction requesting the course.

I will not use time now to inform you of the major training initiative that AFDO has undertaken thanks to a \$2 million grant from the Kellogg Foundation. You'll hear more about the International Food Protection Training Institute in a special presentation during this year's conference. There will be great opportunities ahead for those of you interested in becoming instructors since that is really the limiting factor in delivering much needed training to state and local agencies.

Third: AFDO – The Premier Food Protection Association. There are many examples of strong alliances and initiatives taking place that are pushing AFDO toward the goal to lead food safety reform. Stronger partnerships are being forged along with increased communication with all the food protection conferences and associations. Notably, we are pursuing more formal ties with our friends with the American Association of Feed Control Officials and with the National Association of State Meat Inspection Directors. Kent Kitade with AAFCO and Stan Stromberg with NASMID are here with us representing those organizations.

You will certainly hear more soon from the AFDO Endowment Fund; but I am pleased to inform you that each regional affiliate was provided a grant from the fund to allow future leaders in the affiliates to attend this conference so they can enhance the succession of future AFDO leaders. Let's recognize these future leaders as identified by their affiliates:

- NEFDOA Ronald Rose, CT Health Department
- WAFDO Anna Vickery, NV Dairy Commission
- MCA Travis Brown, OK Health Department
- AFDOSS Wendy Campbell, NC Department of Agriculture
- NCAFDO Benjamin Miller MN Department of Agriculture

Well, if you haven't heard it yet, the AFDO committees are where all the work gets done in this organization. They are the backbone of AFDO. Will all the committee chairs please rise. However, it is the staff of the AFDO office that really holds this association together. They have been instrumental in making our conference run flawlessly and have given me nothing but their full and valuable support during my presidency. Leigh Ann Stambaugh, Pat Smith, and Randy Young – thank you for all you do and for providing me with so much help this past year! I have been very fortunate as President to also have Denise Rooney make the decision to come back and help run AFDO's finances and budget. And as a special bonus – I have been fortunate during my presidency to have Joe Corby come out of retirement with the State of New York to work for AFDO. It doesn't get much better than that. I'd also like to recognize a new addition to the AFDO office and the AFDO family - Erin Shetter will be assisting with the Kellogg Foundation grant. Welcome Erin.

In case you haven't noticed, AFDO has a new look to its website. The new site has many new features that I know you will find useful. Be sure to stop by the table to take a look.

At this point, I would like to point out two people in the audience who represent an agency that has received a special award this past year. It is the NSF, International Leadership Award that was presented at the Food Safety Summit. Joe Reardon and Wendy Campbell are with the North Carolina Department of Agriculture and they were instrumental in raising the bar in the response to the Castleberry Chili contamination incident by invoking an incident command approach involving hundreds of state and local employees. Joe and Wendy are also the ones who put this conference together this year and we want to thank them for that as well.

On the award front, I do need to mention that AFDO supports the Crumbine Award given to outstanding and innovative local public health programs. AFDO also invites the recipient to attend this conference. So I would like to recognize Keith Krinn with the City of Columbus (Ohio) Health Department.

Fourth: Communication. The FDA recognizes 12 associations represented within their Council of Presidents. At the beginning of this year, AFDO's Executive Director, Joe Corby, contacted those associations as well as others and scheduled visits. I was fortunate to accompany Joe on some of those visits. The purpose was two-fold: to reach out and explore better communication and leveraging between associations (especially in light of the integrated national food safety system) and to discuss the creation of the Training Institute. These visits are already showing signs of being fruitful – not only for the community at-large but for what AFDO has learned from some of these visits that will benefit our association. For example, it became quite clear that AFDO is uniquely positioned as having leadership responsibility within the Food Protection Community.

A major accomplishment this year has been AFDO's role in drafting many of the food regulation policies adopted by the National Association of State Departments of Agriculture. AFDO has a strong working relationship with NASDA.

Another major accomplishment has been the release of the outbreak response guidelines put out by the Council to Improve Foodborne Outbreak Response. AFDO has key seats on CIFOR and is represented by two hard working individuals. Will Ernie Julian from the Rhode Island Department of Health and Lisa Hainstock from the Michigan Department of Agriculture please stand.

FDA is under much scrutiny these days – and we have to point out and appreciate all the efforts it has made to improve communication and integrate the food protection system. Here are just some of the ways FDA continues to involve states:

- Grants a new one is the competitive grants (\$500,000 per year for 3 years) to state programs to stand up Rapid Response Teams in coordination with FDA. Another one is the grant to AFDO to conduct a Survey of State and Local Resources.
- Input opportunities The AFDO Board meets yearly with top FDA officials during our Washington D.C. Board meetings. This past year, FDA hosted the 50 State Meeting in St. Louis. You will recall the previous 50 State Meeting was ten years earlier. What a great opportunity that meeting afforded to get input on building the integrated food safety system and to improve all areas within the regulatory and public health communities.

- Contracts FDA continues to support state inspection work through contracts and agreements. FDA has stated its commitment to continue and to increase contracts for states.
- Information sharing FDA continues to increase opportunities for communication through the Council of Presidents. FDA has also listened to calls for using innovative electronic systems to increase communication and response efforts during recall events by using FoodSHIELD to host a recall management system.
- Standards FDA has stepped up efforts to assist states with adoption of the Manufactured Foods Program Standards and has formed a workgroup of representatives from states involved in the pilot of the standards.

These are just some examples of commitment by FDA to work with states toward a fully integrated system. As I visited affiliate conference around the country, something struck me. I noticed the commitment of FDA Center, Regional, and District personnel in attendance at all the affiliate conferences. I particularly noted all the District Directors that attend and become intimately involved in AFDO and its affiliates. At this time I would like everyone from FDA here in attendance to please stand and receive our thanks.

Of course I cannot fail to mention the representatives the other federal agencies that are actively engaged in AFDO such as USDA, CDC, CFIA, Health Canada, and DHS.

So I am happy to report that AFDO is well positioned to meet the goals under the strategy we laid out on the banks of the Mississippi as we go boldly forward into a defining/benchmark year in Food Protection.

## 2010 President's Address, Ronald S. Klein

## Ronald S. Klein President

## AFDO 114<sup>th</sup> Annual Educational Conference Norfolk, VA -- June 19, 2010

Good Evening. I am bullish on AFDO. In 2008 at FDA's 50 State Meeting, I sat down on the banks of the Mississippi River with President Jerry Wojtala and Vice President Joe Reardon to talk about the future of AFDO. To me, the location was very symbolic since the Mississippi River represented the starting point for the Lewis and Clark expedition. As you know, the Lewis and Clark Expedition was commissioned by President Thomas Jefferson as a scientific expedition to explore the newly acquired Louisiana Purchase. The purposes included searching for a northwest water passage to the west and to learn about the area's resources, inhabitants and possibility for settlement. The expedition left St. Louis on a mission which played a key role in the future of a new nation.

Jerry, Joe and I sat down on the banks of the River to discuss what we could to do to set AFDO up to play a key role in protecting the nation's food supply in light of the many incidents which had occurred, which led to the 50 State Meeting and a renewed national commitment to strengthening the safety of our nation's food supply. We wanted to chart out a course to guide future AFDO activities through our leadership terms. We came up with four general objectives.

- 1. Impact food safety legislation.
  - We have provided our input to the house and senate legislation.
- 2. Facilitate food protection training/education.
  - We stood up IFPTI in partnership with Battle Creek Unlimited, our federal partners and the Advisory Council.
- 3. Establish AFDO as the premier food protection association.
  - Playing a key role in promoting standards for regulatory and laboratory standards.
  - AFDO members are playing a key role in Partnership for Food Protection activities.
- 4. Increase/facilitate communication in the food protection community.
  - We have reached out and coordinated our activities with other associations such as NASDA, ASTHO, and APHL.

In fact, this afternoon, Kent Kitade, President of the Association of American Feed Control Officials, and I signed an Memorandum of Understanding between our two Associations to promote communication and collaboration on food safety issues between our Associations.

In the last year, AFDO has also taken steps to strengthen our relationship with the Drugs and Device community and Canada. Cynthia Culmo with Abbott Laboratories has joined the Board as an Affiliate Advisor, and Dr. Bill Teeter with the Canadian Food Inspection Agency has joined to represent Canadian food inspection community.

I am proud to say that AFDO has succeeded in meeting those objectives over the last year, and we are determined to continue to meet them through my second term, and Oscar and Claudia's terms.

One of AFDO's characteristics is: it is not a bureaucracy.

In my mind, AFDO serves as a mediating institution. In the most general sense, "mediating institutions" are institutions that convey the norms and values of a society -- in our case, the food protection community -- so as to socialize them and integrate them into that society. In our case AFDO is "mediating" because it is an intermediary between the government agencies that establish food community norms and the members of the food protection community who are expected to fall into line with those norms.

It answers to the Board and its members and as a group we are inquisitive, nimble, and able to quickly mobilize to address the food safety communities' needs as they occur.

Good examples include development of the Model Produce Standard and the efforts of AFDO members to work with state labs, APHL, FDA, and NOAA to validate simpler methods for assessing petroleum contamination in seafood.

One of the challenges that our state food safety agencies must meet is to demonstrate our commitment and ability to play their part in ensuring a safe food supply. I understand that many consumer groups have expressed concern that state agencies do not have ability or wherewithal to play a significant role in protecting the nation's food supply.

Program regulatory standards are the tool that can be used at all levels of government to demonstrate that food safety agencies have a quality management system in place to ensure that they have the authorities, training, resources, and tracking systems in place to ensure the safety of food under their oversight. Agencies need to have the courage to take a hard look at their systems, identify flaws and gaps, develop program improvement plans and take affirmative action to implement their program improvement plans.

I look forward to serving AFDO in the coming year and being the first President serving multiple year terms since George Flanders completed his second term in 1911.

## FDA Strategic Vision for "Establishing a Fully Integrated National Food Safety System with Strengthened Inspection, Laboratory and Response Capacity"

(Draft September 24, 2009)

#### Strategic Vision

Food safety is a core public health issue even though the U.S. food supply is among the safest in the world. With today's far reaching and complex food supply chain, there is an increasing need to find more effective solutions to better protect American consumers by preventing intentional and unintentional food contamination. Food can become contaminated through many different vehicles at many different steps – at the source on the farm or in harvest water, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, FDA, in cooperation with other food regulatory and public health agencies, has done a great deal to prevent both intentional and unintentional contamination of food at each of these steps. FDA has worked with other federal, state, local, tribal, territorial and foreign counterpart food safety regulatory and public health agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry, consumer groups, and academia to strengthen the nation's food safety and food defense system.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer dietary patterns, changes in industry practices, changes in the U.S. population, and an increasingly globalized food supply chain and new pathogens and other contaminants pose challenges that are requiring us to continually update our current food protection strategies.

Recognizing these challenges, President Obama has made a personal commitment to improving food safety. On July 7, 2009, the multiagency Food Safety Working Group (Working Group), which he established, issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group recommends a new public-health-focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

Preventing harm to consumers is the top priority. Too often in the past, the food safety system has focused on reacting to problems rather than preventing harm in the first place. The Working Group recommends that food regulators shift towards prioritizing prevention and move aggressively to implement sensible measures to prevent problems before they occur.

At the Federal level, a number of Agencies are working together to coordinate their efforts and develop short- and long-term agendas to make food safer. As the federal regulatory agency responsible for most of the food supply, FDA¹ is committed to ensuring that the U.S. food² supply continues to be among the safest in the world. FDA has the responsibility of establishing enforceable standards to ensure the safety of the food the Agency regulates. These standards will reflect the prevention-oriented public health principles embraced by the Working Group. FDA will set new food safety standards and review existing standards in light of what we have learned over the past decade with regard to prevention strategies. In addition, FDA will work with food industry to establish quantitative metrics for the controlling factors affecting food safety by incorporating appropriate measures of success. These metrics, or measures, will improve our ability to verify that certain measures or practices are being carried out and are effective.

This verification requires a systematic, integrated approach to effective risk control and enforcement strategies. Together with our federal and state, local, tribal and territorial partners, FDA will work to plan and implement an inspection and enforcement program to ensure high rates of compliance with the Agency's food safety standards. By working with federal, state, territorial, tribal and local regulatory and public health partners, FDA will establish a fully integrated national food safety system, built on collaboration among all of these partners. The system will encompass inspections, laboratory testing, and response and will place priority on preventing foodborne illness, in both food for humans and animals, through the adoption and uniform application of model programs, such as the Manufactured Food and the Retail Food Regulatory Program Standards and other appropriate program standards.

<sup>&</sup>lt;sup>1</sup> FDA is the federal agency that is responsible for the food supply except for meat, poultry, and processed egg products, which are overseen by our partners at the U.S. Department of Agriculture (USDA).

<sup>&</sup>lt;sup>2</sup> For purposes of this document, the term "food" includes human food, animal feed, components (i.e. ingredients) of both food and feed, and dietary supplements for humans, except as otherwise noted.

This collaboration will result in 1) better ability to assess potential risk at domestic food facilities and greater and more consistent inspectional coverage of these facilities across the entire food supply chain, 2) greater food surveillance through integration of food facility inspection and testing information, and 3) improved rapid response capacity and efficiency.

Under this system, FDA and federal, state, territorial, tribal and local regulatory agencies will conduct food facility inspections under the same set of standards. FDA will work with its regulatory partners to develop uniform national standards, including inspection, investigation, and testing protocols; training and certification requirements; establish program audit criteria; and create performance metrics to ensure program objectives are met. System integrity and credibility will be maintained through regular program oversight and accountability at all levels. Federal and state inspections will be conducted in accordance with a public health risk driven national work plan that FDA will develop with its regulatory partners. An integrated system will result in more coordinated response efforts to better respond to multi-state outbreaks when they occur.

To be fully successful, the national food safety system must be built with continuous input from FDA's regulatory and public health partners. It must be sustained through multi-year funding that will be provided to state and local regulatory and public health partners to build the necessary state and local infrastructures, contain adequate legislative authorities to facilitate information sharing and communication among all partners, and include infrastructure for a national electronic information-sharing mechanism. These actions will result in a national food safety system that reduces foodborne illness, identifies sources of risk throughout the system, and reduces time to detect and respond to outbreaks. A public health driven, collaborative, and leveraged approach to food safety activities and responsibilities will be reflected in improved public sector resource utilization at a national level, which provides additional capacity for ensuring a safe and secure food supply.

## **Background**

## Leveraging with Federal, State, Local, Tribal and Territorial Partners

The domestic food supply chain is currently overseen by a mix of multiple Federal, State, territorial, tribal, and local regulatory and public health agencies that often work independently from one another, work under different legislative authorities, and are driven by different objectives and perspectives on priorities. More than 3,000 state, territorial, tribal, and local regulatory agencies have responsibility to regulate the retail food and foodservice industries in the United States. Together, they are responsible for the inspection and oversight of over one million food establishments, including restaurants, grocery stores, cafeterias and other outlets in healthcare facilities, schools, and correctional facilities. Specifically, states perform approximately 90% of all food safety inspections conducted at food manufacturing and distribution establishments. At the federal level, FDA oversees more than 150,000 registered domestic food facilities including food manufacturers and processors, food warehouses, and grain elevators. The majority of this oversight responsibility is shared with states. In addition, federal and/or state, territorial, tribal and local authorities oversee more than 2 million farms.

## FDA's Role in Setting National Standards

FDA provides guidance, model codes and other technical assistance to state, territorial, tribal and local regulatory partners to assist them in carrying-out their regulatory responsibilities. Since 1972, FDA has also contracted or entered into partnership agreements with many state regulatory agencies to perform inspections and investigations. FDA currently has 42 state food inspection contracts, providing over 10,500 inspections in the areas of Good Manufacturing Practices (GMPs), sanitation, seafood, juice, and low acid canned foods. In addition, FDA has 35 state contracts providing over 5,000 yearly inspections in the areas of GMPs for licensed medicated feed manufacturers and bovine spongiform encephalopathy (BSE) controls. FDA also has 65 state grants/cooperative agreements in the areas of food protection, food emergency response networks, ruminant feed ban support, rapid response teams, and innovative food defense activities. These contracts and cooperative agreements have established, developed and maintained collaborative relationships with state, territorial, tribal and local regulatory partners, and have been critical in leveraging FDA's food safety resources. These agreements have provided critical support to FDA in terms of regulatory oversight, but there are challenges related to the integration of resources and information sharing that need to be addressed.

## Limitations to Current Collaborative Efforts

Current leveraging efforts have not been sufficient to ensure adequate oversight of the entire food supply chain. Food facilities are not uniformly inspected, food regulatory systems (seafood, dairy, food manufacturing) operate under different standards, data is not uniformly captured on a national basis, and the data we have is not systematically mined for signal intelligence. Neither FDA nor our regulatory or public health partners alone collect and analyze a sufficient number of surveillance samples per year to have confidence in being able to effectively identify all potential areas of concern; combining and then evaluating the data would provide a much greater ability to detect problems. In addition, national response efforts are uneven. The current food safety system hinders our ability to effectively prevent and respond to foodborne safety problems in the food supply. Throughout the years, numerous reports point out that the FDA does not take full advantage of the inspectional and surveillance capabilities of our state, territorial, tribal and local regulatory and public health partners. This situation is due in large part to the varied standards and laws in each state as compared with the federal system, as well as to the lack of interoperable data systems and legal impediments to sharing data among partners.

These combined factors present a challenge in managing and responding to signals of public health concern in the food supply. The currently decentralized U.S. public health and agriculture system results in a situation in which responsibility for surveillance, detection, investigation, response and recovery to foodborne disease outbreaks is shared across federal, state, territorial, tribal, and local government agencies. Standards for laboratory testing and protocols vary widely, and alignment is needed to effectively manage and conduct multi-state outbreak investigations. Developing the needed standards, providing incentives to state and local food regulatory agencies and promoting uniformity will be important components to an integrated national food safety system.

As noted, various levels of government are working to address food safety problems from the President's Food Safety Working Group to local leaders working through public health and agriculture organizations. At all levels, there is a call for greater integration and coordination between the Federal agencies and the regulatory and public health partners involved in food safety. This document identifies the concrete steps FDA is taking to carry forth this integration and coordination. It describes the necessary actions of the Agency and its partners for development of an integrated, risk-based national food safety system to improve food safety and reduce foodborne illness.

#### **Integrated National Food Safety System**

To be successful, an integrated national food safety system must build upon the work currently being done by FDA and our regulatory and public health partners. Additional work is needed in terms of active communication. coordination, and support. One important step towards implementing an integrated national food safety system will entail the adoption and implementation of the Retail Food Regulatory Program Standards and the Manufactured Food Regulatory Program Standards, which is already well underway<sup>3</sup>. In addition to these existing standards, consideration will be given to the need for additional program standards in order to adequately cover the entire food supply chain. Program standards are important to establish a uniform foundation for the design and management of federal, state, territorial, tribal and local food programs that encompass best practices of a high quality regulatory program. Within the program standards are the critical elements of a regulatory program designed to protect the public from foodborne illness. For example, in the Manufactured Food Regulatory Program Standards, the specific standards cover a state's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, food-related illness and outbreak investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. It is FDA's role and responsibility to not only meet these standards and to collaborate with other food regulatory agencies, but to also assist through incentives or other means state and local regulatory and public health programs working to meet these standards.

#### **Recent Actions**

The goal to implement an integrated national food safety system is not new but rather a concept that has been in the works for some time. Since the 1990's, federal, state, territorial, tribal and local agencies have been working together to address specific pieces of a national integrated system. The 1998 National Food Safety Initiative launched a comprehensive approach to food safety and had some success in moving integration forward, but faltered after a few years without adequate federal infrastructure and funding to support the effort.

<sup>&</sup>lt;sup>3</sup> At this time, the Retail Food Regulatory Program Standards and Manufactured Food Regulatory Program Standards have been developed for human food only. FDA has GMPs for the production of medicated animal feeds. FDA is currently developing process control regulations for animal feeds and will investigate the potential for expanding the Retail Food and Manufactured Food Regulatory Program Standards to animal feed.

In August 2008, FDA hosted a national meeting, Gateway to Food Protection, which reenergized efforts to work together toward an integrated approach in response to addressing the challenges of the growing global food supply. Outcomes of the meeting included the creation of an FDA Federal-State "Partnership for Food Protection Coordinating Committee" made-up of Federal partners (FDA, CDC, USDA, and DHS) and a wide range of representatives from our state, territorial, tribal and local regulatory and public health partners. The committee serves as a strategic and technical committee that advises the Agency on necessary infrastructure and food safety implementation strategies essential to building a national food safety system. The Partnership for Food Protection work groups were also formed under the purview of the Coordinating Committee to focus on specific topics and achieve specific objectives by fall of 2010. The work groups are focusing on improving interactive information technology (IT), training, response, and risk-based work planning. A work group was also formed to facilitate the development of a Pet Event Tracking Network (PetNet). The lessons learned and other results from these groups will be incorporated into the plan for an integrated national food safety system.

These efforts and the necessity to integrate food safety have been recognized and enthusiastically supported by the Obama Administration, which, through an initial investment in the FY 2010 budget of \$14.6 million, will begin to build FDA infrastructure in support of an integrated national food safety system. Specifically, the recent White House Food Safety Working Group Key Findings Report submitted to President Obama on July 7, 2009, identified an integrated food safety system as a priority recommendation where the Federal government will "... prioritize crucial inspection and enforcement activity across the world, support safety efforts by States, localities and businesses at home; and utilize data to guide these efforts and evaluate their outcomes." The Report also recommended the need for a unified incident command structure and adequate provision for sharing data in an emergency, among other specific recommendations to improve state, territorial, tribal and local response capacity and capabilities.

## Overview of the Approach

FDA will continue to strengthen the collaboration with its regulatory and public health partners to build an integrated national food safety system. To create a strong and credible system, the Agency will:

- Build on collaboration among all regulatory and public health partners to provide comprehensive and well coordinated coverage of the food safety system;
- Develop and implement uniform, national standards and training and certification programs with our regulatory and public health partners;
- Maintain integrity through regular program oversight and accountability at all levels; and,
- Sustain the system through: (1) seeking multi-year funding to state and local regulatory and public health partners linked to defined performance standards; (2) facilitating information sharing and communication for enhanced public health; and (3) creating the infrastructure for national electronic information sharing.

In addition, an integrated national food safety system will require additional staff to support the development of needed programs and approaches and significant expansion of FDA's current infrastructure. The new system also will require new legislative authorities for FDA to fully implement the data and information sharing aspects of the integrated risk-based national food safety system. Under an integrated system, each regulatory and public health partner would continue to operate under its own laws and regulations but additional coordination and oversight will be used to create a more unified system.

## Implementation and Impact

FDA and its regulatory and public health partners will begin implementing the integrated national food safety system by taking the following actions:

**Establish policies and procedures** to ensure that programmatic objectives and implementation are coordinated across federal, state and local public health and regulatory partners and that Agency actions are transparent to the public by:

- Developing a communications strategy and decision making process to ensure full participation of FDA's state, territorial, tribal and local, regulatory and public health partners in the development of the implementation plan.
- Developing a system organizational oversight and management structure.
- Developing a detailed 5-year implementation plan.

**Continue to develop national standards** in cooperation with state and local food regulatory agencies to ensure uniformity in inspectional coverage and the collection and analyses of compliance, surveillance, and environmental samples to enable both FDA and states to make greater use of each other's laboratory analytical and inspection data in pursing advisory, administrative, or judicial actions by:

- Continuing the development and expansion of national program standards such as the Manufactured Food Regulatory Program Standards and Retail Food Regulatory Program Standards.
- Developing a national laboratory proficiency testing program and a remediation program for states that do not meet the national program standards.
- Creating shared data standards that enable the exchange of public health and agricultural laboratory data as well as enforcement data among FDA and our regulatory and public health partners for faster identification of food safety threats and information on corrective actions.
- Leveraging the work of the Partnership for Food Protection IT Work Group to make necessary IT improvements for interconnectivity between Federal, state, territorial, tribal and local regulatory and public health partners.

**Create a national work plan** to improve and expand inspection and sample collection coverage to verify industry performance in implementing food safety measures while reducing redundancies in the current system through better coordination of work planning by FDA and our state, territorial, tribal and local partners by:

- Developing a process to work with all regulatory and public health partners to create an approach for the ranking of food categories by public health risk.
- Developing systems, staffing, tools, policies and procedures for moving forward with the creation of a national risk-based work plan. FDA will seek lessons learned from the pilot project underway by the Partnership for Food Protection Risk-Based Work Planning Work Group.

**Develop training and certification programs** 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 by:

- Developing and implementing training for regulatory and public health partners, including certification of proficiencies and work with one or more international food protection training institutes.
- Working collaboratively with Federal, state, territorial, tribal and local partners to develop and deliver 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.
- Developing and administering food certification programs for inspectors, investigators, and analysts at FDA and our regulatory partners to ensure that all parties are performing to the national standards.
- Leveraging the work being done by the Partnership for Food Protection
  Training Work Group to perform competency assessments and to
  develop a framework for certification.
- Working with outside parties on the creation of one or more international food safety training academies as a forum to provide the training.

**Coordinate emergency response** to enable faster and more effective response to food safety events by:

- Working with the Council to Improve Foodborne Outbreak Response (CIFOR) to implement guidelines for multi-jurisdictional outbreak response.
- Continuing to improve outbreak response by increasing the number of cooperative agreements to fund Rapid Response Teams (RRT) and to fund additional laboratories in the Food Emergency Response Network (FERN) to integrate an all-hazards response capability for food and foodborne illness responses and to react more rapidly to potential threats to the food supply.
- Leveraging the Partnership for Food Protection Response Work Group's
  work on improving recall effectiveness checks through a series of pilots
  and development an inventory of Incident Command System (ICS)
  models and best practices.
- Working with regulatory and public health partners to develop guidelines to use that will improve traceback speed and accuracy.

- Working with regulatory and public health partners to develop guidelines to use that will improve traceback speed and accuracy.
- Developing a system for rapid analysis and integration of consumer complaints to facilitate early detection of food problems.
- Beginning to work collaboratively to address recovery issues after an outbreak has occurred.

**Provide program oversight** to measure performance against the program standards and maintain the credibility of the program by:

 Conducting audits of our regulator partners to measure their performance against the program standards. Audits will include reviews of inspection, investigation, sample collection and analysis, enforcement, response, recovery, and outreach activities.

**Develop performance outcomes and measures** to assess the success of the program in terms of the reduction of foodborne illnesses and other public health focused criteria, industry compliance rates, resource efficiencies, and other applicable criteria.

## **Conclusion**

The safety of the U.S. food supply depends on preventive and collaborative approaches throughout the food supply chain. We look forward to continuing to work with our federal, state, territorial, tribal and local regulatory and public health partners along with industry, consumer groups, academia, and others to help FDA reduce the incidence of foodborne illness to the lowest level possible. The development of a fully-integrated national food safety system over the next five years is a critical component within the President's overall public-health-focused food safety framework for maintaining a safe food supply for U.S. consumers.

# AFDO Model Code for Produce Safety For State and Local Regulatory Agencies





The Association of Food and Drug Officials (AFDO) developed this Model Code for Produce Safety in response to a growing number of outbreaks associated with consumption of fresh fruits and vegetables. The Code represents the culmination of a two-year effort by a number of dedicated organizations and individuals that were asked to develop a science based regulatory framework to address the production of all fruits and vegetables, while maintaining the flexibility to

appropriately address specific commodities of higher concern. It builds upon existing guidance documents and regulations; and, consistent with AFDO's mission to promote uniform food safety laws, rules and regulations, this Model Code for Produce Safety may be viewed as another tool to assist the regulatory community in development of a nationally integrated food safety system.

## Acknowledgements

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## **Additional Resources**

- Commodity Specific Food Safety Guidelines for the Melon Supply Chain, 1<sup>st</sup> Edition, November, 2005
- Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens, June, 2008
- Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain, 2<sup>nd</sup> Edition
- Food Safety Begins on the Farm A Grower's Guide, Rangarajan, Bihn, Gravani, Scott, and Pritts

- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, 1998
- Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance, July 2009
- Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance, July 2009
- Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Draft Guidance, July 2009
- Protecting Perishable Foods During Transport by Truck, USDA, 1995

## I. PREAMBLE

The effort by the Association of Food and Drug Officials (AFDO) to formulate a Model Code of Practice for the production of fresh fruits and vegetables grew out of a request from the east coast tomato industry in late 2006. Industry representatives and regulators agreed that recent outbreaks of foodborne illness attributed to fresh tomatoes were unacceptable. Both parties also recognized that a myriad of regulatory approaches were possible, though not necessarily desirable for a coherent national strategy. In addition, the AFDO Board believed that it was important to address Good Agricultural Practices (GAPs) in the production of all fruits and vegetables. Thus, in keeping with its mission to promote consistency in food safety laws, rules and regulations, AFDO convened a working group to develop a Model Code for food safety at the farm and packing facility.

The Code developed herein may be considered as a model for guidance and/or regulation by federal and state regulatory bodies, and for collaboration among such parties working together with the industry. The Code is intended to outline consistent, science-based practices in order to minimize the likelihood of multiple regulatory bodies developing conflicting and/or duplicative standards. This effort is the result of nearly two years of collaboration among federal and state regulatory officials, representatives from the fresh produce industry (including grower associations, individual growers, and marketers), representatives from retail, manufacturing and transportation sectors, academicians, and consumer advocacy groups.

## A. Scope

This model code is intended to address food safety practices for produce (fresh fruits and vegetables) at the farm and packing facility. The Code does not address the additional processing steps or handling that may occur at a fresh-cut processing facility. This Model Code focuses on minimizing the potential for contamination of fresh produce with pathogenic microorganisms of public health significance; however, states, localities and other users of this document should consider all potential risks associated with the production of produce.

## B. Implementation

In the development of this Code, the AFDO working group adopted an approach similar to that of the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation adopted by the U.S. Food and Drug Administration (FDA). As with the seafood HACCP regulations rule (21 CFR Part 123), regulatory requirements for fresh produce production and packing are presented in broad terms within the Code, with more specific production practices and recommended mitigation options to be presented in a companion "hazards and controls" guidance document. This hazard and control guidance for fresh produce (in development) will assist both the industry and regulators in assessing potential microbial hazards and evaluating and implementing preventive controls or risk mitigation strategies relative to the wide variety of production practices, sitespecific conditions, and individual commodities covered by this Code.

#### C. Responsible Parties

Effective management of food safety requires that responsibility be clearly established between the many parties involved in the production of fresh produce. There may be many different permutations of ownership and business arrangements during the growing, harvesting and packing of fresh produce. For this reason, it is incumbent upon everyone involved to identify which responsibilities rest with which parties, and to ensure that these responsibilities are clearly defined. For example, growers commonly contract with a third party to harvest their crop. The grower must clearly identify which party is responsible for each applicable

provision of the Code, such as providing adequate toilet and hand-washing facilities and worker training. Responsibilities may be delegated to individuals within the firm or may be formally addressed in contractual agreements when third parties are involved. It is important to ensure that each party is aware of its responsibilities so that food safety roles are clearly understood and regulatory response or enforcement action is directed to the responsible party.

## D. Food Safety Plan

The workgroup developing this Code agreed that a food safety assessment and a food safety plan, based on the outcome of that assessment, are critical for all firms growing and packing fresh produce. After considerable discussion, it was further agreed that this plan shall be written. It is not the intent that such a written plan place an undue burden on small producers. The workgroup agreed that an acceptable plan shall be commensurate with the size and complexity of the operation and the inherent risks associated with the commodity and production practices. It is fully expected that for certain operations, some plans will be fairly simple while others will be more elaborate.

It is further the intent of the workgroup that the companion hazards and controls guidance document, when available, will include tools to assist the operator with preparation of a written plan and other aspects of the Code.

## E. Product Tracing

This document is not intended to prescribe a particular system or specific requirements for product tracing. The workgroup and AFDO recognize the myriad of different tools available to facilitate traceability — and that the federal government and industry have established or are considering product-tracing regulations with more specific requirements. The language in this Code is intentionally broad so as to set baseline requirements for traceability but to avoid creating conflicts with those systems currently in place or under consideration.

#### II. DEFINITIONS

The following definitions apply for the purposes of this document:

- A. Adequate: Satisfactory for a particular purpose; fully sufficient; suitable or fit.
- B. Agricultural water: Water used in the growing environment (for example, field, vineyard, or orchard) for agronomic reasons. It includes water used for irrigation, transpiration control (cooling), frost protection, or as a carrier for fertilizers and pesticides. Occasionally, a more specific term may be used, such as "irrigation water." Typical sources of agricultural water include flowing surface waters from rivers, streams, irrigation ditches or open canals; impoundment (such as ponds, reservoirs, and lakes); wells; and municipal supplies.
- C. Clean: Washed, rinsed and/or reasonably free of dust, dirt, food residues, and other debris.
- Documentation: A written procedure or record of a task being completed.
- E. Food-contact surfaces: Those surfaces that are reasonably likely to contact produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. "Food-contact surfaces" include, but are not limited to, utensils, containers, and equipment (such as conveyor belts) that contact produce; and that are used in harvesting, post—harvest activities, or packing operations. They do not include tractors, forklifts, hand trucks, pallets, or anything else that is used for the handling or storing of contained or packed produce that does not come into actual contact with the produce.
- F. Pathogen: A microorganism of public health significance (i.e. capable of causing human disease or injury).
- G. Personal-service area: An area used for activities not directly connected with the production or service function performed by the operation or facility. Such activities include, but are not limited to, first aid, medical services, dressing, showering, toilet use, washing, and eating. A personal-service area may include outdoor areas adjacent to a field in production.

- H. Pest: Any animal or insect of public health significance including, but not limited to, birds, rodents, cockroaches, flies, and larvae that may carry pathogens which can contaminate food or food-contact surfaces.
- I. Post-harvest activity: Any activity that takes place after the edible portion of the plant has been harvested. This may include washing, cooling, sorting, or packing in the field or at another location.
- J. Produce: Fresh fruits and vegetables that are likely to be sold to consumers in an unprocessed (i.e., raw) form. Fresh produce may be intact, (such as strawberries, whole carrots, radishes, and freshmarket tomatoes), or cut during harvesting (such as celery, broccoli, and cauliflower).
- K. Sanitize: To treat food-contact surfaces with a process that is effective in destroying or substantially reducing the number of microorganisms of public health concern as well as other undesirable microorganisms, without adversely affecting the quality of the involved product or its safety for the consumer.
- L. Shall: Indicates mandatory requirements.
- M. Should: Indicates recommended or advisory measures.
- N. Water source (Source water): The origin of the water being used at the farm or packing operation or facility. It may be a municipal supply, private well, pond, stream or other body of water.

## III. GENERAL REQUIREMENTS

#### A. Food Safety Plan

 A written food safety plan shall be developed based on the size, complexity, previous association with foodborne outbreaks, and the outcome of the assessments of an operation as outlined in this model code, including an assessment of the specific risks and controls unique to the operation.

## B. Product-Tracing System

 All entities involved in the produce supply chain, within the scope of this code, shall maintain a system and records to facilitate the identification of the immediate past source of the produce and immediate subsequent recipient of the produce.

- For every lot shipped or received, records shall be readily available, legible, and the information they contain shall be readily interpretable and include:
  - a. Identification of the immediate past source of the produce;
  - b. Commodity identification;
  - c. Lot identification:
  - d. Quantity;
  - e. Date packed;
  - f. Date shipped or received;
  - g. Identity of carrier; and
  - h. The immediate subsequent recipient of the produce.
- 3. For every lot shipped, records shall be readily available, legible, and the information they contain shall be readily interpretable and enable tracing to the sources of all components.
- 4. In the event of commingling or repacking of produce, records shall be maintained for raw product accountability that enable tracing of all incoming products to outgoing products in which they are components.
- 5. Labels and/or labeling shall be accurate and contain sufficient information to assure product tracing.
  - a. Labels that are inaccurate shall be removed or defaced prior to packing.
- 6. The operation shall test its product-tracing system at least annually to ensure it is adequate.

#### C. Documentation

- 1. Adequate documentation that demonstrates compliance with the requirements of this code shall be maintained.
- Documents may be maintained on-site or at an off-site location and shall be available for inspection within a reasonable time frame.
- 3. Documentation shall be maintained for a minimum period of two years, absent state or federal regulations to the contrary.

## IV. CROP-PRODUCTION REQUIREMENTS

#### A. Field Assessment

#### 1. General Requirements

- a. The responsible party shall ensure that fields, as well as the structures and equipment within or adjacent to them, are managed to minimize harborage of pests and wildlife that may be a source of contamination of fresh produce with pathogens while it is being grown.
- b. Any storage sheds, buildings, or other structures, equipment and containers used in the fields to contain produce, or food-contact surfaces shall be cleaned and, where appropriate, sanitized to prevent contamination with pathogens.

#### 2. Land Use Considerations

- a. The responsible party shall evaluate previous land use history and adjacent land use.
- b. When previous land use history or adjacent land use indicates a possibility of pathogen contamination, growers shall perform corrections as needed to minimize the potential for an adverse public health impact.
- c. The evaluation may lead to the conclusion that the land should not be used to grow produce until the risks presented by prior or adjacent land use can be minimized.
- d. The responsible party shall evaluate the farm sewagetreatment or septic system at least annually to verify it is maintained in a manner to prevent contamination of fields or produce, and in compliance with local laws and regulations.
- e. An evaluation should also be conducted following any significant flood event. Fresh produce that has been in contact with flood waters is considered to be adulterated due to potential exposure to sewage, animal waste, and pathogens, and shall be excluded from the human food supply.

## B. Agricultural Water for Field Use

## 1. General Requirement

Water quality shall be adequate for its intended use and shall meet all applicable federal and state laws and regulations.

#### 2. Assessment of Water Source

- a. The responsible party shall identify, assess the adequacy for its intended use, and document all water sources.
- b. When microbial testing is deemed necessary to verify adequacy of source water quality:
  - (1) Testing shall be performed and documented using standard indicators of fecal pollution, such as generic E. coli tests. The frequency of testing and point of water sampling shall be determined based on the water source, its particular history, and the outcome of the risk assessment.
  - (2) The results of a microbial analysis of a water source available from a public source, such as the local water authority, may serve as acceptable documentation in lieu of testing by the grower.

## 3. Assessment of Water Distribution System

- a. The responsible party shall prepare a description of the water system in use. This description should be sufficient to facilitate an assessment of the risk. This description may use maps, photographs, drawings (hand drawings are acceptable) or other means to communicate the location of water source(s), permanent fixtures and the flow of the water system (including holding systems, reservoirs or any water captured for re-use).
- b. The responsible party shall perform an initial assessment, followed by a review (or new assessment) any time there is a change made to the system or a situation occurs that could introduce an opportunity to contaminate the system. A water-system assessment shall include an inspection of the water system under the control of the responsible party for the purpose of identifying conditions that may result in contamination with pathogens of concern.

- c. Water systems intended to convey untreated human or animal waste shall be separated from conveyances utilized to deliver agricultural water.
- d. In the event that the assessment identifies conditions that may result in contamination with pathogens of concern, action shall be taken to correct these conditions.

## 4. Assessment of Water Use in Crop Production

- a. Growers shall assess the use and quality of water, water application methods, application schedules with respect to crop characteristics and the degree of contact with the edible portion of the crop for the purpose of identifying conditions that may result in contamination with pathogens.
- Based on this assessment, growers shall take appropriate action to eliminate or minimize the potential for contamination.

## 5. Microbial Testing of Agricultural Water

- a. The responsible party shall review the assessments of water source, water distribution system, and water use in regard to the crop characteristics, pathogens of concern, proximity to harvest, and other relevant factors and determine the need for microbiological testing of water.
- b. When microbial testing is deemed necessary, it shall be performed at a frequency and sampled at a location based on the assessments, and it shall be documented. When microbial testing is deemed necessary to verify adequacy of source water quality, testing shall be performed as described in Section IV B 2 b)(1) of this code.

#### C. Soil Amendments

#### 1. Biosolids

a. A responsible party who uses biosolids (treated sewage sludge) as fertilizer or as a soil amendment in the production of produce shall meet the requirements of 40 CFR Part 503, and comply with any additional state requirements. Where biosolids are used, the risk of contamination shall be assessed and appropriate controls shall be implemented.

#### 2. Manure

- a. If a responsible party uses a product containing manure, including leachates and teas, it shall be treated or otherwise handled so as not to serve as a source of contamination of produce. Any product containing manure shall be treated and applied in accordance with all federal, state and local requirements.
  - (1) If the responsible party uses a product containing treated manure, there shall be documentation of the composition, treatment, time and method of application.
  - (2) If the responsible party uses a product containing raw or incompletely treated manure, it shall be used in a manner so as not to serve as a source of contamination of produce. If such a product is used, there shall be documentation of the composition, time and method of application.
  - (3) For purposes of this code, the use of a product containing any combination of raw and treated manure shall be subject to the same requirements as a product containing raw or incompletely treated manure.
- b. The responsible party shall store manure-containing products in a manner or location such that it does not become a potential source of contamination with pathogens.
- c. The responsible party shall take steps to ensure that equipment that comes into contact with raw or incompletely treated manure does not become a potential source of contamination with pathogens.

#### D. Animals

 The responsible party shall assess the impact of domestic and wild animal activity on the potential for pathogenic contamination of produce, considering the crop characteristics, type and number of animals, pathogens of concern, nearness to the growing field, proximity to harvest, and other relevant factors.

- Based on the assessment, the responsible party shall put into place measures to exclude domestic animals from growing fields.
- Where domestic animals are used in farming operations, the responsible party shall put in place measures to prevent or minimize the potential for contamination of produce with pathogens from animal urine and feces.
- 4. The responsible party shall monitor growing fields and adjacent land for evidence of animal activity and shall take appropriate action to prevent or minimize the potential for contamination of produce with pathogens from animal feces.
- 5. When the assessment or monitoring indicates a possibility of contamination with pathogens, growers shall perform corrections as needed to minimize the potential for an adverse public health impact.
- 6. The responsible party shall follow all local, state and federal regulations concerning animal control.

## E. Worker Health and Hygiene

- 1. Personal Health and Hygiene
  - a. Workers shall be required to wash their hands thoroughly before starting work, after using the toilet, after each break, and at any other time when their hands may have become a source of contamination. Hand sanitizers shall not be used as a substitute for hand washing.
  - Eating, drinking, spitting, chewing gum and using tobacco shall be prohibited except in clearly designated areas separate from production fields.
  - c. Personal-service areas for workers shall be maintained so as not to be a source of contamination and located away from produce-handling areas.
  - d. Workers, visitors, and field personnel who show signs of illness (e.g., vomiting, jaundice, diarrhea) shall be restricted from direct contact with produce or food-contact surfaces.
  - e. Any worker, visitor, or field personnel with an open sore or lesion that cannot be effectively covered (e.g., to prevent contact with produce or related equipment) shall be restricted from direct contact with produce or food-contact surfaces.

- f. If gloves are used, the responsible party shall have a policy in place to ensure that gloves are used properly.
- g. The responsible party shall designate competent supervisory personnel to ensure compliance by all workers, visitors, and field personnel with the requirements in this section.

## 2. Training

- a. Growers shall provide training for all workers (including supervisors, full-time, part-time and seasonal personnel), on proper sanitation and hygiene practices. Training shall be documented.
- b. All workers shall be trained on job responsibilities that impact food safety.
- Training in personal hygiene and sanitary practices shall include:
  - (1) Proper hand-washing techniques;
  - (2) Proper use of toilet facilities;
  - (3) Proper glove use, if gloves are used, including the need to wash hands before gloves are donned, and to wash hands in between changing gloves, and that the use of gloves in no way lessens the need or importance of hand washing and proper hygienic practices;
  - (4) Seeking prompt treatment for cuts, abrasions and other injuries; and
  - (5) Reporting signs of illness (e.g., vomiting, jaundice, diarrhea) to their supervisor before beginning work.
- d. Periodic refresher or follow-up training shall be conducted.

#### 3. Visitors

Growers shall ensure that visitors, including buyers, product inspectors, and auditors, comply with all established personal hygiene practices.

## F. Sanitary Facilities

- Toilet Facilities and Hand-Washing Stations
  - a. All toilet facilities and hand-washing stations shall be:
    - (1) Kept clean, well supplied with toilet paper, water, soap and paper towels, and shall be accessible and properly located:
    - (2) Directly accessible for servicing;
    - (3) Serviced and cleaned on a schedule sufficient to ensure suitability for use; and
    - (4) Located as to minimize the potential risk for field and produce contamination.
  - Water used for hand washing shall meet the microbial standards for drinking water prescribed in 40 CFR Part 141.63.

## 2. Sewage Disposal

- a. Sewage and septic systems shall be maintained in a manner to prevent contamination of growing fields or produce with pathogens, and in compliance with local laws and regulations.
- b. Portable toilet facilities shall be serviced in a location and manner that does not pose a risk of contamination of growing fields or produce with pathogens.
- c. The responsible party shall have a plan for immediate control and treatment of any effluent in the event of leakage or a spill. Leakages or spills shall be managed and disposed of in accordance with applicable federal, state and local laws and regulations, and in a manner that prevents or minimizes contamination of growing fields or produce with pathogens.

## V. HARVEST AND IN-FIELD HANDLING REQUIREMENTS

#### A. General Harvest Considerations

#### 1. Preharvest

- a. Immediately prior to harvest, the responsible party should evaluate the production environment for changes in conditions that may be reasonably likely to result in contamination of the produce with pathogens. The scope and nature of the evaluation will vary depending on the commodity and complexity of the operation.
- b. Harvest crews shall be trained to recognize and avoid harvesting produce that is reasonably likely to be contaminated with pathogens.

## 2. Harvesting Containers and Equipment

- a. Harvesting containers, packing containers, and equipment should be stored in a manner so as not to serve as a source of contamination with pathogens to the extent practicable and appropriate.
- b. The types and construction of harvest containers and equipment should be appropriate to the commodity being harvested and their condition maintained so as not to serve as a source of contamination with pathogens.
- c. Food-contact totes, bins, other harvest containers and harvest equipment shall be clean prior to use. When in use, containers and harvest equipment shall be sufficiently maintained so as not to become a source of contamination with pathogens.
- d. Food-contact totes, bins and other harvest containers and equipment that are no longer cleanable shall not be used for harvest, but can be used for other non-food uses if clearly marked or labeled.
- Food-contact totes, bins and other harvest containers and equipment designated for harvesting shall not be used for other purposes unless clearly marked or labeled for that purpose.
- f. Pallets shall be kept clean and in good condition as appropriate for their intended use.

g. Properly trained personnel shall inspect all food-contact totes, bins and other harvest containers and equipment prior to harvest and as needed to ensure that they are suited for their intended purpose and functioning properly.

#### B. Harvest and In-Field, Post-Harvest Activities

- 1. Steps should be taken to identify and not harvest produce that is reasonably likely to be contaminated with pathogens.
- Harvesting, packing equipment, utensils and machinery shall be designed, maintained, calibrated, and used as intended, and handled in a manner so as not to become a source of contamination of produce with pathogens.
- 3. Properly trained personnel shall inspect all equipment to ensure that it is functioning properly, and that all food-contact surfaces are clean and sanitary prior to use, and maintained during use in a manner so as not to become a source of contamination of produce with pathogens.
- 4. Washing, grading, sorting, and packing lines shall be cleaned and sanitized, at least daily when in use, so as not to become a source of contamination with pathogens.
- Cooling equipment shall be inspected at an appropriate frequency, all debris removed, cleaned and sanitized as necessary when in use.

#### C. Harvested Crops

- 1. The responsible party should remove as much dirt, mud and debris as practicable from the produce before it leaves the field.
- 2. The responsible party shall ensure that harvested produce is handled in a manner such that it is not reasonably likely to become contaminated with pathogens.
- 3. If temperature control is important for food safety, steps should be taken to minimize temperature increases and the time between harvest and destination.

#### D. Water Use in Harvest and In-Field Post-Harvest Operations

#### 1. General Considerations

- a. If water directly contacts the harvested crop, or is used on food-contact surfaces, the responsible party shall ensure that water, when applied, meets the microbial standards prescribed for drinking water in 40 CFR Part 141.63. Where necessary, water shall be treated to achieve those standards and monitored appropriately.
  - (1) Special considerations or variances may be appropriate for some crops, such as cranberries and watercress, where deliberate flooding of the field is part of production and harvest practices.
  - (2) The responsible party for harvest/post-harvest activities in the field, that include the use of water that comes into contact with harvested produce or food-contact surfaces, shall perform and document periodic assessment of water use and water system including water source and quality, delivery systems and equipment.
- b. If applicable to intended use, the water-delivery system shall be of adequate size and design and installed and maintained so as not to serve as a source of contamination of produce, water supplies, or equipment with pathogens, or to create an unsanitary condition. The water system shall prevent backflow from, or cross-connection between, piping systems that discharge wastewater, or sewage and piping systems that carry water for post-harvest activities.
- c. When produce is washed, the responsible party shall use wash methods appropriate to the commodity. The responsible party should consider wash-water temperature for certain produce to prevent internalization of microorganisms from the water into the produce.
- d. Any antimicrobial chemicals used in water and that contact food or food-contact surfaces shall be used in accordance with FDA and EPA regulations, label instructions for concentration and contact time, and other requirements.
- e. If used, ice shall be made from water that meets microbial standards for drinking water prescribed in 40 CFR Part 141.63. Ice shall be manufactured, transported, and stored under sanitary conditions.

#### 2. Monitoring

- a. Equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, shall be routinely inspected and maintained to ensure effective operation.
- b. Food-contact surfaces of equipment such as dump tanks, flumes, wash tanks, and hydro-coolers, shall be monitored at an appropriate frequency, have all debris removed, and be cleaned and sanitized as necessary when in use.
- c. Water in dump tanks, flumes, wash tanks, and hydrocoolers shall be monitored and managed as necessary to maintain sanitary conditions. Standard Operating Procedures (SOPs), including water-change schedules, shall be developed for all post-harvest uses of water.
- d. Where necessary for food safety, temperature of postharvest water used in the field in equipment, such as dump tanks and flumes, shall be monitored and kept at temperatures appropriate for the commodity.
- e. If antimicrobial chemicals are used in water, their concentrations and other pertinent conditions (e.g., pH) shall be monitored at appropriate intervals to maintain efficacy.

#### E. Worker Health and Hygiene

#### Personal Health and Hygiene

- a. Workers shall be required to wash their hands properly before starting work, after using the toilet, after each break, and at any other time when their hands may have become a source of contamination with pathogens. Hand sanitizers shall not be used as a substitute for hand washing.
- Eating, drinking, spitting, chewing gum and using tobacco shall be prohibited, except in clearly designated areas separate from production fields.
- c. Personal-service areas for workers shall be maintained so as not to be a source of contamination with pathogens and located away from produce-handling areas.

- d. The responsible party shall have a written policy regarding the use of hair coverings (e.g., hair nets, beard nets, caps), and the wearing of artificial fingernails and jewelry.
- e. Workers, visitors, or field personnel who show signs of illness (e.g. vomiting, jaundice, diarrhea) shall be restricted from direct contact with produce or food-contact surfaces.
- f. Any worker, visitor, or field personnel with an open sore or lesion that cannot be effectively covered (i.e. to prevent contact with produce or food-contact surfaces) shall be restricted from direct contact with produce or food-contact surfaces.
- g. If gloves are used, the responsible party shall have a policy in place to ensure that gloves are used properly.
- h. The responsible party shall designate competent supervisory personnel to ensure compliance by all workers, visitors, and field personnel with the requirements in this section.

#### 2. Training

- a. The responsible party shall ensure training is provided for all workers, including supervisors, full-time, part-time and seasonal personnel, on proper sanitation and hygiene practices. Training shall be documented.
- b. All workers shall be trained on job responsibilities that impact food safety.
- Training in personal hygiene and sanitary practices shall include:
  - (1) Proper hand-washing techniques;
  - (2) Proper use of toilet facilities;
  - (3) Proper glove use, if gloves are used, including the need to wash hands before gloves are donned, and to wash hands in between changing gloves, and that the use of gloves in no way lessens the need or importance of hand washing and proper hygiene practices;
  - (4) Seeking prompt treatment for cuts, abrasions and other injuries; and
  - (5) Reporting signs of illness (e.g. vomiting, jaundice, diarrhea) to their supervisor before beginning work.

d. Periodic refresher or follow-up training shall be conducted.

#### 3. Visitors

The responsible party shall ensure that visitors, including buyers, product inspectors, and auditors, comply with all established personal hygiene practices detailed in subsection 1.

#### F. Sanitary Facilities

- 1. Toilet Facilities and Hand-Washing Stations
  - a. All toilet facilities and hand-washing stations shall be:
    - (1) Kept clean, well supplied with toilet paper, water, soap and paper towels, and shall be accessible and properly located;
    - (2) Directly accessible for servicing;
    - (3) Serviced and cleaned on a schedule sufficient to ensure suitability for use; and
    - (4) Located so as to minimize the potential risk for field and produce contamination with pathogens.
  - Water used for hand washing shall meet the microbial standards prescribed for drinking water in 40 CFR Part 141.63.

#### 2. Sewage Disposal

- a. Sewage and septic systems shall be maintained in a manner so as to prevent contamination of growing fields or produce with pathogens, and in compliance with local laws and regulations.
- Portable toilet facilities shall be serviced in a location and manner so as to prevent contamination of growing fields or produce with pathogens.
- c. The responsible party shall have a plan for immediate control and treatment of any effluent in the event of leakage or a spill. Leakages or spills shall be managed and disposed of in accordance with applicable federal, state and local laws and regulations, and in a manner that prevents or minimizes contamination of growing fields or produce with pathogens.

#### G. Transportation from the Field

#### Personnel

- a. Personnel involved in the loading and unloading of produce during transport shall practice good hygiene and sanitary practices consistent with Part E.1. of this section.
- b. Drivers and transportation-handling personnel shall be made aware of food safety requirements for proper handling and transport of produce.

#### 2. Transportation Vehicles

- a. The carrier shall ensure that the cargo areas of vehicles used to transport produce from the field are as clean as practicable. The carrier shall maintain the cargo area of the vehicle so as to minimize the potential for contamination of produce with pathogens.
- b. Cargo areas and containers that have been used to transport trash, animals, raw animal products or other items that may be a source of contamination with pathogens shall not be used to transport produce, unless the cargo area or container is first cleaned and sanitized by a procedure sufficient to ensure that contamination of produce does not occur.

#### 3. Loading Vehicles

- a. The personnel responsible for loading of produce shall inspect the cargo areas of vehicles used to transport produce from the field to ensure they are as clean as practicable so as to minimize the potential for contamination of produce with pathogens.
- b. Personnel responsible for the loading and unloading of produce shall take steps to minimize the potential of physical damage to produce, which can introduce and/or promote the growth of pathogens.

#### VI. PACKING FACILITY REQUIREMENTS

#### A. Unloading of Transport Vehicles at the Packing Facility

- Personnel who come in direct contact with the produce while unloading shall practice good hygiene and sanitary practices consistent with Part C.1. of this section.
- Personnel responsible for unloading shall inspect the cargo areas of transport vehicles, produce containers and, as appropriate to the operation, the produce, to ensure there are not conditions that may have resulted in contamination of produce with pathogens.
- 3. Personnel responsible for unloading should take steps to minimize the potential of physical damage to produce, which can introduce and/or promote the growth of pathogens.

#### B. Water Use

#### 1. General Considerations

- a. The responsible party shall prepare a description of the water system in use. This description should be sufficient to facilitate an assessment of the risk. This description may use maps, photographs, drawings (hand drawings are acceptable), or other means to communicate the water source(s) and locations thereof, permanent fixtures and the flow of the water system (including holding systems, reservoirs or any water captured for re-use).
- b. The responsible party shall perform an initial assessment, followed by a review (or new assessment) any time there is change made to the system, or a situation occurs that could introduce an opportunity for contamination. A water-system assessment shall include an inspection of the water system under the control of the packing facility for the purpose of identifying conditions that may result in contamination with pathogens.
- Plumbing shall be of adequate size and design and adequately installed and maintained to:
  - Carry sufficient quantity of water to required locations throughout the facility;

- (2) Avoid constituting a source of contamination to produce, water supplies, equipment or utensils, or creating an unsanitary condition; and
- (3) Provide that there is not backflow from, or crossconnection between, piping systems that discharge wastewater or sewage, and piping systems that carry water for post-harvest operations.
- d. If water directly contacts the harvested crop or is used on food-contact surfaces, it shall meet the microbial standards for drinking water prescribed in 40 CFR Part 141.63. Where necessary, water shall be treated to achieve those standards and monitored appropriately.
- e. Any antimicrobial chemicals used in water and that contact food or food-contact surfaces shall be used in accordance with FDA and EPA regulations and label instructions for concentration and contact time or other requirements.

#### 2. Monitoring

- a. Equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, shall be routinely inspected, calibrated on an appropriate frequency, and maintained to ensure effective operation.
- b. Food-contact surfaces of equipment such as dump tanks, flumes, wash tanks, and hydro-coolers, shall be monitored at an appropriate frequency, debris removed to the extent practicable, and cleaned and sanitized as necessary during periods of use (seasons of operation).
- c. Water in dump tanks, flumes, wash tanks, and hydrocoolers shall be monitored and managed as necessary to maintain sanitary conditions. Standard Operating Procedures (SOPs), including water-change schedules, shall be developed for all uses of product-contact water in packing operations.
- d. Where necessary for food safety, temperature of water used in equipment such as dump tanks and flumes shall be monitored and kept at temperatures appropriate for the commodity.

 e. If antimicrobial chemicals are used in water, their concentrations and other pertinent conditions (e.g., pH), shall be monitored at appropriate intervals to maintain efficacy.

#### 3. Wash Water

a. The packing facility shall use wash methods appropriate to the commodity. The facility should consider the washwater temperature for certain produce to prevent internalization of microorganisms from the water into produce tissue.

#### 4. Cooling Operations

- a. Cooling shall be conducted in a manner to minimize the potential for contamination with pathogens.
- b. Interiors of hydrocoolers and other cooling equipment shall be routinely cleaned and sanitized according to written sanitation SOPs or as frequently as needed. Air cooling equipment and cooling areas shall be clean and sanitary and inspected on a periodic basis. Air intakes shall not be located near potential sources of contamination.
- c. Ice shall be made from water that meets the microbial standards for drinking water prescribed in 40 CFR Part 141.63. Ice shall be manufactured, transported, and stored under sanitary conditions.
- d. Containers holding finished product during chilling operations shall be clean and sanitary.

#### C. Worker Health and Hygiene

#### 1. Personal Health and Hygiene

- a. Workers shall be required to wash their hands properly before starting work, after using the toilet, after each break, and at any other time when their hands may have become a source of contamination with pathogens. Hand sanitizers shall not be used as a substitute for hand washing.
- Eating, drinking, spitting, chewing gum and using tobacco shall be prohibited in the packing facility except in clearly designated areas.

- c. Personal-service areas for workers shall be maintained so as not to be a source of contamination and shall be located away from produce-handling areas.
- d. Packing facilities shall have a written policy regarding the use of hair coverings (e.g., hair nets, beard nets, caps), and the wearing of artificial fingernails and jewelry.
- e. Workers, visitors, and field personnel who show signs of illness (e.g. vomiting, jaundice, diarrhea) shall be restricted from direct contact with produce or food-contact surfaces.
- f. Any worker, visitor, or other personnel with an open sore or lesion that cannot be effectively covered (i.e. to prevent contact with produce or food-contact surfaces) shall be restricted from direct contact with produce or food-contact surfaces.
- g. If gloves are used, the responsible party shall have a written policy in place to ensure that gloves are used properly.
- h. The responsible party shall designate competent supervisory personnel to ensure compliance by all workers, visitors, and other personnel with the requirements in this section.

#### 2. Training

- a. The responsible party shall ensure training is provided for all workers, including supervisors, full-time, part-time and seasonal personnel, on proper sanitation and hygiene practices. Training shall be documented.
- b. All workers shall be trained on job responsibilities that impact food safety.
- Training in personal hygiene and sanitary practices shall include:
  - Proper hand-washing techniques;
  - (2) Proper use of toilet facilities;
  - (3) Proper glove use, if gloves are used, including the need to wash hands before gloves are donned, and to wash hands in between changing gloves, and that the use of gloves in no way lessens the need or importance of hand washing and proper hygienic practices;

- (4) Seeking prompt treatment for cuts, abrasions and other injuries; and
- (5) Reporting signs of illness (e.g. vomiting, jaundice, diarrhea) to their supervisor before beginning work.
- d. Periodic refresher or follow-up training shall be conducted.

#### 3. Visitors

The responsible party shall ensure that visitors, including buyers, product inspectors, and auditors, comply with all established personal hygiene practices.

#### D. Sanitary Facilities

- 1. Toilet Facilities and Hand-Washing Stations
  - a. All toilet facilities and hand-washing stations shall be:
    - Kept clean, well supplied with toilet paper, soap and paper towels, and shall be accessible and properly located;
    - (2) Directly accessible for servicing;
    - (3) Serviced and cleaned on a schedule sufficient to ensure suitability for use; and
    - (4) Located so as to minimize the potential risk for field and produce contamination.
  - b. Water used for hand-washing shall meet the microbial standards for drinking water prescribed in 40 CFR Part 141.63.

#### 2. Sewage Disposal

- a. Sewage and septic systems shall be maintained in a manner to prevent contamination of the packing facility or produce with pathogens, and in compliance with local laws and regulations.
- b. Portable toilet facilities shall be serviced in a location and manner that does not pose a risk of contamination of the packing facility or produce with pathogens.

c. The responsible party shall have a plan for immediate control and treatment of any effluent in the event of leakage or a spill. Leakages or spills shall be managed and disposed of in accordance with applicable federal, state and local laws and regulations, and in a manner that prevents or minimizes contamination of the packing facility or produce with pathogens.

#### E. Packing-Facility Sanitation

#### General Considerations

- a. The responsible party should remove as much dirt, mud and debris as practicable from produce before it enters the packing facility.
- The responsible party shall adopt measures that minimize contamination of produce with pathogens from animals.
   Facilities shall have a policy restricting domestic animals from the packing facility.
- c. Prior to use, the lines used for washing, grading, sorting, or packing shall be cleaned and sanitized. When in use, the lines shall be maintained so as not to be a source of contamination with pathogens.

#### 2. Facility Maintenance

- a. Facilities used to store produce shall be cleaned and, as necessary, sanitized prior to use.
- b. Packing-facility premises shall be maintained to minimize harborage of pests and wildlife.
- c. Equipment and machinery shall be maintained and handled so as not to be a source of contamination with pathogens.

#### 3. Pest Control

- a. The responsible party shall exclude pests to the extent possible and appropriate to the facility.
- b. The responsible party shall minimize the availability of food items and water to animals and pests.
- c. The responsible party shall establish a pest-control program, which shall include regular and frequent monitoring to assess and ensure the program's effectiveness.

d. The responsible party shall maintain a pest-control log that includes dates of inspection, inspection reports and steps taken to eliminate any problems. Applications of pesticides (e.g., insecticides, rodenticides) shall be performed in compliance with local, state, and federal pesticide regulations.

#### 4. Packing Containers and Equipment

- Packing containers and equipment should be stored in a manner so as not to become a source of contamination with pathogens.
- b. The types and construction of packing containers and equipment should be appropriate to the commodity being packed and their condition maintained so as not to serve as a source of contamination with pathogens.
- c. Food-contact totes, bins, other packing containers and packing equipment shall be clean and sanitary prior to use. When in use, containers and packing equipment shall be maintained so as not to become a source of contamination with pathogens.
- d. Food-contact totes, bins and other packing containers and equipment that are no longer cleanable shall not be used for packing but can be used for other non-food uses if clearly marked/labeled.
- e. Food-contact totes, bins and other packing containers and equipment designated for use for packing shall not be used for other purposes.
- f. Pallets shall be kept clean and in good condition as appropriate for their intended use.
- g. Properly trained personnel shall inspect all food-contact totes, bins and other packing containers and equipment prior to packing and as needed to ensure that they are suited for their intended purpose and functioning properly.

#### F. Transportation from the Packing Facility

#### Personnel

- a. Personnel involved in the loading of produce during transport shall practice good hygiene and sanitary practices consistent with Part C.1 of this section.
- b. Drivers and transportation-handling personnel shall be made aware of food safety requirements for proper handling and transport of produce.

#### 2. Temperature Control

- a. Prior to loading, if refrigeration is required for safety, the vehicle cargo area shall be pre-cooled. The proper temperature for pre-cooling should be appropriate to the type of produce, or as specified by agreement between the shipper and carrier.
- b. During transport, if refrigeration is required for safety, the carrier shall ensure that the vehicle cargo area is maintained at temperatures appropriate for the particular type of produce, or as specified by agreement between the shipper and carrier.
- c. If refrigeration is required for safety, refrigerated transport vehicles shall have properly maintained and fully functional refrigeration equipment that is in operation for the entire transport time. This equipment shall be controlled by a thermostatic device as necessary to maintain temperatures in the cargo area for the particular type of produce being transported, or as specified by agreement between the shipper and carrier.

#### 3. Transportation Vehicles

a. The carrier shall ensure that the cargo areas of vehicles used to transport produce from the packing house are as clean as practicable. The carrier shall maintain the cargo area of the vehicle so as to minimize the potential for contamination of produce with pathogens. b. Cargo areas and containers that have been used to transport trash, animals, raw animal products, or other items that may be a source of contamination with pathogens, shall not be used to transport produce, unless the cargo area or container is first cleaned and sanitized by a procedure sufficient to ensure that contamination of produce does not occur.

#### 4. Loading Vehicles

- a. The personnel responsible for loading of produce shall inspect the cargo areas of vehicles used to transport produce from the packing facility to ensure they are as clean as practicable so as to minimize the potential for contamination of produce with pathogens.
- b. Personnel responsible for the loading of produce shall take steps to minimize the potential of physical damage to produce, which can increase risk of contamination with, or growth of, pathogens.

# **International Food Protection Training Institute**

# Building the Training Infrastructure for the Integrated National Food Safety System

Gerald Wojtala
Executive Director, IFPTI

### **Beginnings**

In the Fall of 2007, representatives from the Kellogg Company, the Michigan Department of Agriculture (MDA), the Governor's Office, and Battle Creek's economic development corporation, Battle Creek Unlimited, met to discuss the creation of a national research center involving food protection. This discussion was prompted by the Melamine incident that triggered uncertainty of the safety of the global ingredient supply facing U.S. food manufacturers. The Michigan Department of Agriculture agreed to host a meeting in January 2008 and invited food industries and stakeholders to give input about creating a national food protection center. Speakers included David Lineback from JIFSAN, Robert Buchanan from FDA-CFSAN, and a panel consisting of senior executives from ConAgra, Kellogg, McCormick, and Gerber. Over 150 attendees were divided into groups and brainstormed about what a national center could provide to the food industry.

Shortly after this meeting, a group representing the Kellogg Company, W. K. Kellogg Foundation, MDA, the Governor's Office, Michigan State University, Western Michigan University and Battle Creek Unlimited flew to Washington, D.C. to meet with the directors and senior staff of CFSAN and CVM to discuss the need for a national center. When the meeting was concluding, almost as an afterthought, Robert Buchanan said, "If you're looking for something unique to create a national center around, you might want to think about creating a Training Academy for food inspectors. One doesn't yet exist but is certainly needed." On the way back from Washington, the group of representatives agreed that a training academy could be the foundation of a national center.

#### **IFPTI's Creation**

The President of AFDO during this time brought up the idea of creating the training academy with the AFDO Board. There was enthusiasm about the idea and Joe Corby reminded the Board that this was one of the ideas that came out of the 1998 50-State meeting. As a result of AFDO discussion among its representatives, the idea became one of the recommendations during a June 2008 workshop of state and local representatives in Las Vegas at a session led by Mike Taylor of Georgetown University as part of a grant project entitled "Enhancing the Roles of State and Local Officials in an Integrated National Food Safety System."

In response to food safety bills being introduced in Congress, the AFDO Executive Committee developed talking points promoting the roles of states in an integrated food safety system. Training and the creation of a training academy were key bullets in these talk points. Joe Corby, Jerry Wojtala and Steve Benoit scheduled follow up trips to meet with CDC, FSIS, and FDA during the summer of 2008 to discuss this even further. Members of Congress and the media were also briefed.

In August 2008, Joe Corby and Mike Taylor made a presentation at the start of the 50-State meeting where the idea of a training academy was posed to the participants. As a result of all of AFDO's strategic communication, the need for a national Training Center emerged as a major recommendation in all the workgroups.

Immediately after the 50-State meeting, AFDO sent a letter to Battle Creek Unlimited stating its desire to lead the creation of the Training Center. Then in the Fall of 2008, AFDO put together a \$2 million grant request to W. K. Kellogg Foundation. The AFDO Board urged full support for this effort at the October Board meeting in Washington, D.C. Steve Steinhoff agreed to assume the role of Project Manager after AFDO received word that the grant request was approved.

During the first week of January 2009, the AFDO Executive Committee and Steve Steinhoff traveled to Battle Creek to meet state and local stakeholders. AFDO formed a steering committee and Steve Steinhoff led weekly conference calls to go over work planning. Joe Corby and Jerry Wojtala began meeting with numerous stakeholders – specifically directors and presidents of the 12 associations FDA recognizes on the Council of Association Presidents. At this point, the working title of the center was replaced with "International Food Protection Training Institute".

#### **Progress Towards Goals**

During 2007 and 2008, there was a significant amount of visionary and preparatory work done. In 2009, the activities and accomplishments included strategic planning, implementing active outreach to the food protection community, forming and convening two meetings of the Advisory Council, improving and tailoring course delivery prototypes, designing and filling out the infrastructure, refining registration and selection processes, and monitoring and managing grant activities. The composition and function of an Advisory Council was designed to represent the food protection community and provide much needed feedback. The Advisory Council remains a key source of expertise, perspective, input, and review as issues or proposals are presented on subjects such as training needs; course and participant selection; development and delivery of training courses; and curriculum development.

A significant foundation-building activity was undertaken: the development of a curriculum framework. The concept that emerged at a meeting hosted at Cornell was to develop a curriculum that organizes courses or courses of study for food protection professionals based on employee job level or experience (i.e., entry, journey, technical, or leadership) and food category (i.e., unprocessed, manufactured/wholesale, or retail). So the curriculum needed to be career-spanning. Additionally, standards were pursed in order to bring uniformity and quality to the process of course development, assess course content, deliver competency-based training, and provide an appropriate certificate or certification. IFPTI applied to the International Association of Continuing Education and Training as well as to the American National Standards Institute.

In 2010, much progress was made in aligning IFPTI strategic activities with FDA's Training Vision. IFPTI was endorsed by FDA's Partnership for Food Protection Training Workgroup and began working with this workgroup on its deliverables. Most notably, IFPTI lead the collection and categorization of existing food safety courses available throughout the U.S. Workgroup members were given access to FoodSHIELD, where the accumulating inventory was posted. Nearly 900 courses were identified and placed into a catalog.

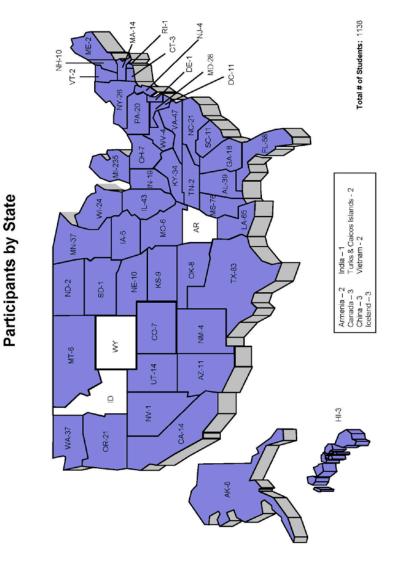
The curriculum development process continued in 2010 with the assistance of a stakeholder team made up of representatives of state and local agencies, academia, and FDA. Competencies were identified, validated, and mapped to curriculum content areas. A categorization process was used to place existing courses into curriculum content areas in order to identify priorities and training gaps. Course quality elements were identified and a process for new development or existing course acceptance into the curriculum was created. Next steps include sequencing, bundling courses for job-specific program certificates, and establishing course review procedures.

By the end of 2010, over 1,100 food protection professionals from 47 states and 7 other countries attended training hosted or sponsored by IFPTI. Participants represented federal, state, local, territorial, and tribal agencies as well as academia and industry. (See figures 1 and 2 for a breakdown of participants.) In June, IFPTI took swift action to coordinate emergency training for states in response to the Gulf Oil Spill. Nearly 60 officials were identified and funded by IFPTI to attend critical seafood sensory training given by expert responders with the National Oceanic and Atmospheric Association. This training allowed state officials to make decisions about closing fishing areas as well as evaluate the safety of seafood harvested in the Gulf.

IFPTI also began development of a 3-week fellows program called Fellowship for Food Protection. Participants were solicited from state and local agencies throughout the U.S. and selected fellows began the program in August. The fellows selected year-long projects and will present the results of their work during a poster session at the 2011 AFDO Conference in Plano, Texas.

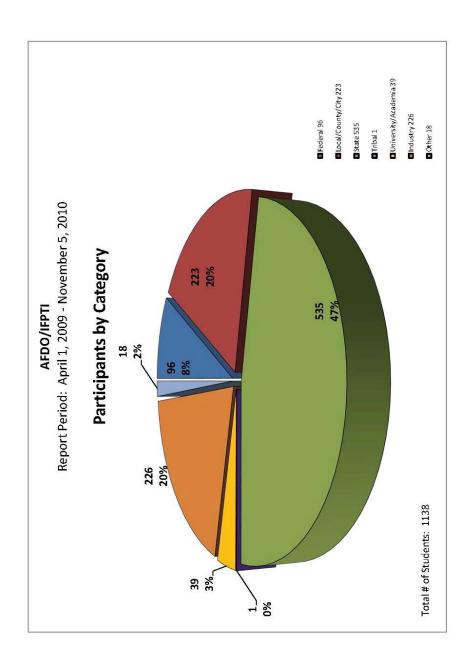
A significant milestone in 2010 came when IFPTI received a Public Health Services Grant through the FDA. The four main deliverables under the grant are:

- 1. Develop a Training Network to provide technical, management, and leadership training to regulatory and public health officials.
- 2. Serve as the hub for the administration of a Training Network.
- Develop and deliver standards-based training programs not currently offered.
- Build an Instructor Cadre to ensure the availability of highly trained instructors within regulatory and public health agencies across all jurisdictions.



AFDO/IFPTI Report Period: April 1, 2009 – November 5, 2010

Key:
Represented States
Non-Represented States



#### **Going Forward**

The International Food Protection Training Institute is making substantial progress in helping FDA realize its Training Vision in support of a fully integrated national food safety system. Work has begun to create a consortium of universities to serve as development and delivery centers of excellence. International opportunities are being considered, but serious work will wait until a strong, domestic foundation is built for the training system.

The IT infrastructure for the training system is being built by combining three systems: a Learning Management System, a Data Management System, and a Registration Portal. These systems will allow for a coordinated administration of participant registration and records spanning throughout one's career.

Course owners will begin the process of reviewing courses for quality and fit into the "National Curriculum". Development of new courses will be based on standards and will consider the best modality for delivery to participants in order to assure the most efficient transfer of knowledge and skills. These modalities will include blended learning techniques, synchronous/asynchronous computer-based learning, pod casts, videoconferencing, serious gaming, virtual reality, hands-on techniques, and case studies incorporating lessons learned and experiences from real life.

In order to train in an integrated system, many more high quality instructors will be needed. An instructor development process has begun to leverage qualified individuals from within and outside of agencies at all levels.

IFPTI will continue to move rapidly in order to meet the challenge of supporting the integration of the food safety system by assuring the best trained food protection officials across the U.S. and abroad. The impact on public health demands an unwavering commitment to this mission going forward.

# AFDO Resource Survey of State and Local Food Safety Programs -- 2008 Summary



#### **About the Survey**

For more than 113 years, the Association of Food and Drug Officials (AFDO) has served as a major voice for food safety officials in the United States and Canada. The Association proudly represents food safety officials from state and local government at public meetings or briefings where they

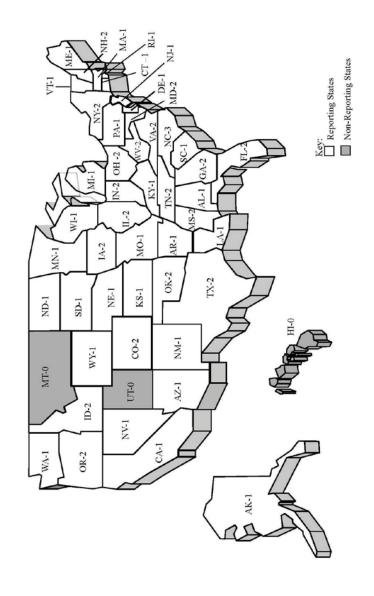
present consensus opinion or submit official comments on a host of food safety issues. Today, more than ever, there is a call for unity among public health officials in government at all levels and the need to coordinate the available food safety resources in an effort to integrate the nation's food safety system. AFDO has long supported the vision of a nationally integrated food safety system in this country as a logical step in addressing the food safety challenges that exist.

In developing an integrated food safety system, one cannot ignore the enormous capacity and food safety work currently performed at the state and local government levels. It is for this reason that AFDO has once again conducted this resource survey of state food safety programs.

We are very pleased to provide this information to you. It, once again, demonstrates the enormity of resource, the extent of effort, and the presence of innovation that exists at the state and local levels. It is also our hope that it provides another argument for advancing efforts to integrate the nation's food safety system. Here is how the survey was conducted:

- Utilizing the FDA Directory of Regulatory Officials, a message from AFDO
  was submitted to state agency program managers in the fields of food
  safety, meat, dairy, retail food, animal feed, animal health,
  epidemiology, and laboratory services. Where possible, program
  managers were asked to compile agency data from all food protection
  disciplines into one survey form. An electronic version of the survey was
  provided with directions on how the survey was to be completed.
- Outreach and promotion was conducted with other government regulatory associations that also represent state and local officials. These associations agreed to promote the survey through newsletters and other communications with their membership.

- Completed survey forms were submitted to the AFDO office where the data was compiled. Follow up for clarification of any submitted data was accomplished by contacting the agency representatives identified on the survey form.
- Other sources of data were obtained through federal agencies and FDA Cooperative Programs (shellfish and dairy). This data was compiled as well.
- A total of 64 survey forms, representing 47 of the 50 states were received. Many responders represented more than one agency within their Department (i.e. Dairy, Food, Meat, Animal Feed).
- Where possible, state responders provided inspection and investigation number estimates for local government jurisdictions. In many cases, the state responders were unable to provide these numbers.
- AFDO has taken extreme care to make sure that no submitted data was duplicated in the survey.



## **INSPECTIONS PERFORMED**

Food Processing/Repacking Facilities (excludes dairy)	49,510
Dairy Plants	5,704
Dairy Farms (government agencies only)	90,756
Retail Food Service Establishments	1,590,317
Temporary Food Establishments	84,887
Institutional Food Service Establishments	78,278
Retail Food Stores	422,486
Custom Exempt Meat Plants	32,730
Small Animal Slaughterhouses	8,775
Feed Manufacturers and Distributors	18,511
BSE Inspections	6,424
Rendering Plants	847
Food Transportation Vehicles	4,090
Food Salvage Operations	1,105
Farm Production (GAPs)	595
Fruit/Vegetable Packing Houses	1,922
Food Warehouses	16,393
Frozen Dessert Plants	2,635
Shell Egg Plants	6,362
Mobile Food Units	31,106
Water Vending Machines	2,362
Milk Tank Trucks	7,532
Home Based Processors	3,124
Ice vending machines	1,105
Inspection exempt poultry processors	164
Live poultry markets	1,212
Unlicensed facilities	307

#### **INSPECTION DATA OBTAINED FROM FEDERAL AGENCIES**

The following statistics represent all 50 states.

Food Inspections for FDA <sup>1</sup> (FDA Contract)	9,516
Feed & Animal Drugs for FDA <sup>1</sup> (FDA Contract)	6,025
State Meat Inspections for USDA <sup>2</sup> (Intra-State Wholesale Meat Processors)	1,672,092
Talmadge-Aiken for USDA <sup>2</sup>	452,682
Country of Origin Labeling (COOL) for USDA <sup>2</sup>	2,000
Manufactured Milk Plants <sup>1</sup> (FDA Cooperative Program)	2,800
Shellfish/Crustacea Processing Plants <sup>1</sup> (FDA Cooperative program	4,902

<sup>&</sup>lt;sup>1</sup> = Data courtesy of the U.S. Food and Drug Administration

Total Inspections (including data from federal agencies) 4,619,256

#### **INVESTIGATIONS**

Total Investigations	55,882
Other	3,282
Animal Health Matters (food safety related)	95
Disasters and/or Emergency Response	513
Chemical Residues in Meat, Milk, Fish, and Eggs	162
Farm Pesticide Residue	314
Shellfish Growing Areas	749
Consumer Complaints (excluding FBI)	50,376
Trace backs (not recalls)	391

<sup>&</sup>lt;sup>2</sup> = Data courtesy of the U.S. Department of Agriculture

#### **ENFORCEMENT ACTIONS**

Embargo/Seizure/Condemnation	6,080
Stop Sale	7575
Health Advisories	157
Monetary Penalties	103,975
License/Permit Revocation	716
Injunction	31
Criminal Prosecutions or Complaints	34
Warning Letters	25,665
Hearings	5,289
Closures	1,337
Voluntary Destruction/Disposal	15,636
License/Permit Suspension	1,968
Other	2,046
Total enforcement actions	170,509
How many food recalls were coordinated and then monitored	

#### FOOD LABORATORY

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by your agency?

Food Chemistry	80,652
Microbiology	202,093
Pesticide Residue	14,750
Animal Feed Samples	42,750
Pet Food	6,135
Antibiotic Residue	43,622
BSE Ruminate Protein Products	4,068

## Total number of samples analyzed 394,070

1,244

## ADMINISTRATIVE, FUNDING AND PERSONNEL

Can your agency receive complaints electronically via email etc.?	, your website,
Yes	56
No	3
Do inspectors utilize field computers when conducting inspect	
Yes	39
No	20
Do you maintain an active current inventory of regulated estal	blishments?
No	4
Do you maintain an inventory of unlicensed establishments?	
Yes	17
No	41
Total number of licensed/permitted establishments	793,281
Total number of food establishments regulated	837,644
How many full time equivalents (FTEs) dedicated to food sa and investigation does your agency employ?	fety inspection
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#### ADMINISTRATIVE, FUNDING AND PERSONNEL (continued)

Do you require Continuing Education for Field Inspectors or Investigators?
Yes 42
No 15

Has your agency enrolled in the FDA Retail Food Regulatory Program Standards?
Yes 38
No 20

Has your agency enrolled in the FDA Manufactured Food Regulatory Program Standards?
Yes 22

This survey demonstrates a real commitment to food safety at the state and local level, but it is the intangible activities that routinely occur here that should not be overlooked – the innovative efforts to gain industry compliance, the interactions of the agencies with industry and Consumers, the promptness of strong enforcement actions. These are all elements that state and local governments employ to protect their citizens. They exhibit dedication and diligence to assure food safety.

AFDO has for many years, supported the goals of resource management at all levels of government to provide synergistic and effective response to all food safety emergencies, including threats and acts of terrorism. We strongly support the concept of integrating all available resources to address food safety and food security as a national concern. Federal agencies and the states have a tradition of working very closely together on public health issues, and any improvement toward integrating the states with their federal counterparts will literally add thousands of food safety and security "foot soldiers" to what is clearly a national effort.

No

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#### **AFDO's Mission Statement**

The Association of Food and Drug Officials (AFDO), established in 1896, successfully fosters uniformity in the adoption and enforcement of food, drug, medical devices, cosmetics and product safety laws, rules, and regulations.

AFDO and its six Regional Affiliates provide the mechanism and the forum where regional, national, and international issues are deliberated and resolved uniformly to provide the best public health and consumer protection in the most expeditious and cost effective manner.

#### AFDO accomplishes its Mission by:

- Promoting education, communication and cooperation among government, industry and consumers.
- Fostering understanding and cooperation between industry, regulators and consumers.
- Promoting the adoption and uniform enforcement of laws and regulations at all levels of government.
- Providing guidance and training programs for regulatory officials and the regulated industry, to promote nationally and internationally uniform inspections, analyses, interpretations and investigations.
- Identifying and resolving inconsistencies in consumer and public health protection laws, regulations, standards and policies.
- Providing a permanent working committee structure to research current issues, obtain input from interested parties and produce recommendations for action.
- Developing model laws, regulations and guidance documents and seeking their adoption throughout the United States.

Conducting an Annual Educational Conference, where for over a century, AFDO has provided the opportunity for individuals from government, industry, and the public to participate, listen, and learn valuable information and develop initiatives concerning food, drug, medical device, cosmetic and product safety issues.

# ASSOCIATION OF FOOD AND DRUG OFFICIALS MEMBERSHIP FORM

How did you hear al	Check One: New Membership Renewal Membership
·	Ms./ Mrs./ Miss/ Dr.:
Name: Title: Company: Address:	Date:
<ul><li> In order to r</li><li> Group and C</li><li> All Members</li></ul>	e that all above contact information is complete. eceive eNEWS and other AFDO announcements you must supply a valid email address. ontributing memberships must be submitted together as a single package. hips run on a calendar year basis.
	2: This membership category is for individuals to purchase single memberships.
Individual Members Alumni/Students Regulatory/Governmer Consumers/Educationa Small Business/Consult Associate Industry	
	his membership category is for those agencies or organizations that would like reduced rates for an increased is. <b>Group membership renewals must be submitted together as a single package.</b>
# of Group Members 5-10 11-20 21-50 Greater than 50	Government         Non-Government           □ \$46 each         □ \$300 each           □ \$44 each         □ \$285 each           □ \$42 each         □ \$270 each           □ \$40 each         □ \$255 each
	hip: This membership category is for those agencies or organizations that would like to support the ongoing tion through an "increased" level of contribution. Contributing membership renewals must be submitted ckage.
<b>Contributing Member</b>	Government Non-Government
Platinum Gold Silver	□ 5 memberships for \$750       □ 5 memberships for \$2,500         □ 3 memberships for \$500       □ 3 memberships for \$1,750         □ 2 memberships for \$350       □ 2 memberships for \$1,250
Check payable in U.S	
Card Number:  Billing Address:  City, State, Zip:	Exp: For Office Use Only:  Date Rec Entered  Date Pd Initials
Name on Card:	CC Check

# Mark Your Calendar



# 115<sup>th</sup> Annual Educational Conference June 18-22, 2011

Marriott Dallas/Plano at Legacy Town Center
Dallas, TX