Indiana State Department of Health Food Protection Program

FoodBytes

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5 of 7 FSMA Rules Finalized by FDA

The U.S. Food and Drug Administration (FDA) has finalized five of the seven major rules that implement the core of the FDA Food Safety Modernization Act (FSMA). These are the Preventive Controls for Human Food and Animal Food rules, the Foreign Supplier Verification Programs (FSVP) rule, the Produce Safety rule and the Accredited Third Party Certification rule. The remaining two rules on Sanitary Transportation and Intentional Adulteration are scheduled for release in spring 2016.

The FDA is to receive an additional $104.5 million as part of the fiscal year 2016 spending bill. Funds are most likely due to ongoing implementation of FSMA.

FSMA was signed into law on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

Preventive Controls Rule final rule September 17, 2015

Includes two final rules;
1. Preventive Controls: Human Food; see http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

2. Preventive Controls for Animal Food; Covered facilities must establish and implement a food safety system that includes an analysis of hazards and a written food safety plan. Compliance dates are staggered over the next several years. See http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm

3. Foreign Supplier Verification Programs final rule November 13, 2015

The FVSP affects importers of human and animal foods. This rule requires that food imported in the U.S. meets applicable U.S. safety standards. For more information see http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm.

4. Produce Safety final rule November 27, 2015

The FDA FSMA Produce Safety rule is now final and the earliest implementation dates for some farms begin one year after the effective date of the final rule. The definition of "farm" and related terms were revised in the final "Preventative Controls for Human Food" Rules. Operators whose only activities are within the farm definition are not required to register with FDA as food facilities and are not subject to the preventative control regulations. The rule establishes requirements for:

- Agricultural Water Quality/testing
- Biological Soil Amendments/manure and compost
- Sprouts
- Domesticated and Wild Animals
- Worker Training and Health and Hygiene
- Equipment, Tools and Buildings

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Inside this issue:

Food in the news: FDA Approves Genetically Engineered Salmon

The Food and Drug Administration (FDA) made an industry defining decision in November 2015 by approving the first genetically engineered (GE) animal intended food, declaring the genetically engineered salmon as safe to eat as non-GE salmon. FDA regulates GE animals under the new animal drug provisions of the Federal Food, Drug and Cosmetic Act, since the recombinant DNA (rDNA) introduced into the animal meets the definition of a drug. In this case, the rDNA makes the salmon grow faster. This ruling allows the salmon to be raised in land-based tanks in Canada and Panama but not in the United States. The company farming the salmon is AquaBounty Technologies and the salmon is called AquaAdvantaged salmon according to Bernadette Dunham, director for FDA's Center for Veterinary Medicine. She notes that the salmon grown in tanks will eliminate the potential spread of disease and parasites from farmed

salmon to wild salmon. It is noted that using the land-based facilities makes it unlikely that the fish could escape and establish themselves in the wild. This approval is not without its critics. The activist group Friends of the Earth call the salmon a "frankenfish" and says consumers and large grocery chains are lining up to reject the product.

FDA issued two draft guidance's on labeling the salmon. Currently FDA does not require food containing ingredients derived from genetically engineered sources to be labeled at GE. "Both guidance documents explain FDA's best thinking on how to make it easy for consumers to know whether a food was produced using genetic engineering, or not," says Felicia Billingsleas, B.S., M.S., director of FDA's Divison of Food Labeling and Standards.

For more information see the FDA webpage http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm472487.htm

By Sharon Farrell, FPP ISDH

Did You Know? Salmonellosis in Indiana 2015 Rates

Worth mentioning is the preliminary lower case count for Salmonellosis in Indiana in 2015 at **575** cases.

According to Tess Gorden, Enteric Epidemiologist, ISDH, "Our total case count has been lower this year compared to last year." Tess said that this will require further investigation. The table at right is a summary of rates from 2008-2014.

Sources:

- I SHIP 2014-2016 http://www.in.gov/isdh/25733.htm
- MMWR January 8, 2016 / 64 (52);ND-923-ND-940 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6452md.htm?s_cid=mm6452md_w
- HUS rates 2013/2014 Epidemiology Resource Center ISDH

Assure Food Safety

Condition	2008	2009	2010	2011	2012	2013	2014	Average
Botulism	1	0	0	1	0	0	1	0.4
Campylobacteriosis	686	646	864	750	741	875	862	774.9
Cryptosporidium	203	282	285	263	164	139	185	217.3
Giardiasis*	NR	316	399	325	227	203	168	273
Hepatitis A	20	19	11	24	11	32	20	19.6
Hepatitis E	2	2	0	3	3	4	1	2.1
Hemolytic Uremic Syndrome (HUS)	1	7	0	2	11	9	7	5.3
Listeriosis	10	10	15	11	10	11	8	10.7
Salmonellosis	641	590	786	650	782	707	733	698
Shiga-toxin producing E.coli (STEC)	104	97	144	147	191	151	168	143.1
Shigellosis	607	76	64	91	161	117	1366	354.6
Typhoid Fever	1	1	0	4	0	4	5	2.1
Vibriosis	5	3	0	2	2	9	6	3.9
Yersiniosis	9	7	13	11	10	6	13	9.9

By Sharon Farrell, FPP ISDH

Epi-Ready Trainings Update

ISDH Food Protection, Laboratory and Epidemiology staff provided six Epi-Ready Trainings throughout Indiana this year. Overall, a total of 195 persons attended training, comprised of representatives from 64% of Indiana's local health departments and 74% of Indiana's key state foodborne illness investigators.

The goal of this training was to help foodborne outbreak investigation teams prepare for and rapidly detect foodborne disease outbreaks, quickly launch a coordinated investigation involving epidemiology, environmental health and the laboratory and implement control measures in a timely fashion to reduce the incidence of foodborne illness.

The Epi-Ready Training was a two-day in-person workshop developed by the National Environmental Health Association (NEHA) and the Centers for Disease Control and Prevention (CDC) for environmental and public health professionals responsible for investigating foodborne illness outbreaks. Through a team-based approach, participants learned how to efficiently and effectively respond to foodborne illness outbreaks.

The Epi-Ready Training was built around the inherent need for collaboration among environmental health specialists/sanitarians, epidemiologists and laboratory staff during a foodborne outbreak investigation. Additionally, collaboration during these investigations must include all others who may be directly or indirectly involved in outbreak investigations (e.g., public health nurses, health educators, industry, risk communication/ public information officers).

Due to this fact, attendees were encouraged to attend training within their districts, so that in the event of an incident, responders know their local, state and federal partners. Those attending were able to get to know state central office and their district field staff personnel. In addition, a new manual was provided that contained new and valuable Indiana specific guides to assessing a local outbreak. This information can also be downloaded from the CD. A few hard copies are still available as well.

If you missed attending this opportunity, but would be interested and able to attend this training in Marion Co., spring 2016, please contact us (https://www.surveymonkey.com/r/Epi-Ready_Interest). This training will likely not be held again until 2020.

By Laurie Kidwell, ISDH RRT Supervisor

Task Force Tabletop/Drill Exercise Update

On November 12-13, 2015, the Indiana Food Safety and Defense Task Force held a tabletop/drill exercise at the Ivy Tech Culinary School in Indianapolis that included a complex foodborne illness/intentional contamination scenario. The exercise brought together participants from local, state and federal public health professionals, industry, healthcare, law enforcement and consumer advocacy groups. The scenario was developed with help from experts from the Indiana State Department of Health, Indiana State Police, Indianapolis Metropolitan Police Department, Marion County Prosecutors Office, Indiana Fusion Center, Purdue University, Indiana Poison Control and the Ivy Tech Culinary School.

The exercise scenario involved a disgruntled worker contaminating food with organophosphate chemicals resulting in multiple cases. Initially, the scenario looked like an ordinary foodborne illness outbreak and quickly evolved into a serious public health incident. The exercise began with tabletop discussions and small complaint interview, case definition, hypothesis and environmental assessment plan of action drills and then transitioned into several larger communications, press releases, environmental assessments, sampling demonstrations and law enforcement drills.

Exercise Participants
Communication/Press Release Drill

The exercises purpose was to test current written state and local procedures, outbreak investigation actions and recent Epi-Ready Trainings. In all, 63 players participated and 11 individuals in key leadership roles observed the exercise. Several strengths and weaknesses have been identified and an after action report and corrective action plan is being developed from these findings. During the exercise, players identified the following key points to be important in preparing and responding to this type and/or similar scenarios.

- Pre-establish internal and external partnerships, communication and information sharing

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Task Force Tabletop/Drill Exercise Update

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procedures among key stakeholders before, during and after food emergencies.

- Know your jurisdiction's internal capabilities and establish triggers for seeking assistance from external partners.
- Jointly develop, test, maintain and revise written plans to include foodborne illness outbreak partnerships, communication, surveillance, response and mitigation procedures.
- Partners should jointly train by having key foodborne illness responders take in person and distance learning foodborne illness outbreak response and incident command classes.
- Equip partners with surveillance and investigation/sampling tools, as well as investigation forms, manuals and guidances.
- Develop partnerships and create memorandum of understandings with law enforcement officials and pre-establish written intentional contamination indicators, procedures and safety practices

Kelli Whiting (Marion CHD) and Aaron Mayer (Ivy Tech)
Intentional Contamination Drill

In conclusion, the exercise was successful in discovering several strengths and weaknesses and was useful in testing current procedures and recent trainings. The ISDH Food Protection program would also like to recognize everyone that helped plan and facilitate the exercise as well as the FDA's Food Safety and Defense Cooperative Agreement for funding the event. Please feel free to contact Laurie Kidwell at 317-233-3213 if you have any additional questions about the exercise or would like help preparing your own jurisdiction's response capabilities.

L-R JoAnna Beck (ISDH FPP), Alan Houchin (ISDH FPP), Jeff Bricker (Ivy Tech), Natalie Hathaway (Ivy Tech), Roshonda Hite (Ivy Tech)
Environmental Assessment Drill

Max Reynolds (Fusion), Detective Mike Woida (IMPD), Detective Wyonne Hale (IMPD)
Law Enforcement Drill

By Laurie Kidwell, ISDH RRT

Special Thanks

The Indiana State Department of Health Food Protection Program would like to thank the following individuals for making the Indiana Food Safety and Defense Task Force Exercise possible.

Laurie Kidwell, ISDH FPP
Misty Harvey, ISDH FPP
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Stanley Danao, ISDH FPP
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Gwenn Christianson, Indiana Poison Control
James Scott Monroe, Purdue University
Jeffery Bricker, Ivy Technical Culinary School
Jessica Jagger, Ivy Technical Culinary School
Jenna Rutherford, Ivy Technical Culinary School
Ivy Tech Student Actors: Aaron Mayer, Natalie Hathaway, Roshanda Hite, and Monica Muhl.
Ivy Tech Student Ambassadors
Indiana Food Safety and Defense Exercise Players and Observers

Food Safety Staff Happenings

ISDH Food Protection Program staff met at Clifty Falls State Park in October for a multi-day all staff meeting. The staff has many varied duties and this gave the program a chance to share about key 2015 activities and plan for 2016. Topics of discussion included group and area reports, assigning inspection frequency based on menu risk, compliance and enforcement issues (noting repeat and severe/critical violations, and addressing habitual non-compliance), Indiana Food Transportation Assessment Projects (IFTAPs) and symposium brainstorming.

Policies and procedures, best practices and lessons learned were discussed. For example, inspection report marking considerations were explored to ensure accuracy and consistency. Staff discussed when a violation should be marked as a repeat (same section of the law that was cited on consecutive inspections).

The focus is on the food safety practice, and one section number may include multiple instances, and may differ from inspection to inspection. Marking a repeat of the section number encourages consistency, and the appropriate follow-up action may be determined dependent on the situation.

The program is also undergoing a reorganization, both in the central office and for field staff. Supervisory responsibilities are being realigned. Field staff task maps have been created to capitalize on staff and program strengths. Maps outline coverage areas for local health department coverage, wholesale food establishment inspections, state retail food establishment inspections and standardization. This information will be updated on the interactive map (http://www.in.gov/isdh/23962.htm).

By Krista Click, Food Protection Director

Pictured L-R Stan Danao, Krista Click, Andrew Miller, Eric Eldridge, Jennifer Coleman, Jordan Young, Delnaaz Daruwala, Sharon Farrell, Hank Wolfe, Misty Harvey, George Jones, Sharon Pattee, JoAnna Beck, Mark Mattox, Lisa Harrison , Al Houchin, Laurie Kidwell, Dan Miller, Kris Gasperic

FSMA Rules

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See: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

5. Accredited Third-Party Certification Rule November 2015

The rule establishes the framework, procedures and requirements for accreditation bodies including:

- Scope
- Requirements for Recognized Accreditation Bodies
- Requirements for Third-Party Certification Bodies
- Related FDA Actions
- Exemptions
- Implementation

See: http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM473503.pdf

Cooperative Agreements

FDA has entered into a five-year cooperative agreement with the **National Association of Agriculture (NASDA)** that brings together a range of state partners to collaboratively plan implementation of the forthcoming Produce Safety Rule. For more information see http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm **or**

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm#Cooperative_Agreements

FSMA Training

As part of the roll-out, the FDA crafted a multi-faceted training plan for food industry. **The Produce Safety Alliance (PSA), Food Safety Prevention Controls Alliance (FSPCA), and Sprout Safety Alliance (SSA)** are developing training programs to help industry understand the requirements of the preventative controls regulations and the produce safety rule. Each agency has a website where training information is found; at:

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm#Major_Components

The goal is public and private partnerships to ensure global training programs that meet the needs of those who must comply with the new FSMA Standards.

In January 2015, the FDA announced that it had joined with USDA's National Institute of Food and Agriculture (NIFA) in a collaborative partnership to establish the National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program as mandated in Section 209 of FSMA. As mandated in FSMA, this cooperative grant program will provide the curriculum and deliver the training including 'train—the trainers' programs. Extension and other partners will play an important role. According to FDA, these programs may provide a certificate of completion to food industry participants.

Please contact the ISDH Farm Consultants for additional information on training for Produce Safety. Jennifer Coleman or JoAnna Beck can be reached at 317-234-8569 or at: http://www.in.gov/isdh/files/

Variances from FDA for one or more of the rules

The rule also permits states, tribes or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting variances from one or more of the requirements of this rule.

Indiana and the FSMA rules—how are we affected?

Simple fact, no one knows at this point what changes will be needed or if Indiana will adopt the rules. The new rules may require changes to Indiana codes. At this point, this article and references are for the purpose of awareness. However, for those who have taken past GAP (Good Agricultural Practices) courses, be aware that new provisions of this rule are being added and you can expect advertising of new *improved* courses. See http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

For FSMA Framework for Industry Curriculum Development and Dissemination (October 2015) Info graphic, see http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM465064.pdf

Conclusion

FDA is notifying us that they are on a path to working with public and private partners globally to ensure adequate training programs. More to come.

For more information on FDA's Food Safety Modernization Act, visit http://www.fda.gov/fsma.

If you have questions, please contact Krista Click, Food Protection Director at 317-234-8570.

By Sharon Farrell, FPP, ISDH

Farm scenes in Indiana by Jennifer Coleman, FPP ISDH

School Gardens

One question that has been asked of health inspectors across the state more and more frequently is “Can we have a school garden?” And the short answer is – yes. There are no state laws that prohibit schools from growing and using their own produce. However, school staff and students responsible for overseeing garden activities should be aware of general good agricultural practices (GAPs) that will help prevent contamination of their produce. There are five areas to consider when evaluating school garden safety: student/staff health & hygiene; water quality; fertilizer and manure; animals; and tool/equipment sanitation.

Staff and students should not work in the garden or handle produce or clean equipment if they have experienced symptoms of diarrhea, vomiting, sore throat, fever or an infected cut in the last 24 hours or if they have been diagnosed with illness due to Hepatitis A, *Salmonella* spp., *Shigella* spp., Shiga toxin-producing *E. coli* or Norovirus. Students and staff should have access to restrooms with adequate handwashing facilities, and should be aware of proper handwashing techniques as well as when to wash their hands.

Test all non-municipal water sources at least annually for bacterial contaminants such as *E. coli* or Coliform. Potable water should be used for irrigating plants, washing produce, tools and equipment. Do not use rainwater collected from roof gutters or downspouts due to the risk of contamination from bird droppings. After harvesting, avoid washing produce until preparation for serving. It may be best to do all the washing in the cafeteria instead of outside in the garden. Use non-porous, cleanable containers for transporting and storing produce. Clean and sanitize containers and harvest tools (scissors, shears, harvest buckets, etc) prior to harvest. Be sure to test sanitizer concentrations, and store clean containers and tools off the ground and in a location protected from animals and environmental contamination.

Avoid fertilizing with raw animal manure. There are several pellet or liquid products on the market that have been heat or chemically treated to kill pathogens. Check with the manufacturer to ensure

the product has undergone pathogen testing to verify the kill step. Also consider a small fence to keep wildlife and domestic animals out of the garden, and do not harvest produce that is in close proximity to animal feces on the ground or plants. Any insecticides, fungicides or other pesticides used in the garden should be EPA-registered and used according to the label. Store fertilizers and other chemicals in a locked location that is separate from produce as well as harvest tools and containers. Children should never apply or have access to the chemicals.

Schools must be diligent in following GAPs and post-harvest sanitation recommendations. For more information about GAPs or school gardens, visit http://www.in.gov/isdh/25773.htm or contact the Food Safety Farm Consultant in your area.

By Jennifer Coleman, Farm Consultant, ISDH FPP

Healthy Meetings

Dr. Jerome Adams, State Health Commissioner, recently distributed to ISDH staff a Health Meeting Guideline and Recommendations to promote healthy choices. Dr. Adams noted that the connection between food, physical activity and health are well documented. He stated, "I believe it is imperative that we, the Indiana State Department of Health, model healthy behaviors for our colleagues, partners, and the public." A reference is made to the 2010 Dietary Guidelines (see related article Defending the Dietary Guidelines on p. 10-13 of this FoodBytes issue).

"A healthy meeting guideline states that any meeting conducted for state purposes on state time will provide healthy food options and encourage physical activity through active breaks." The healthy meeting recommendations include general planning considerations, menu suggestions that include produce and whole grains and ways to incorporate physical activity into ISDH hosted meetings. The National Alliance for Nutrition and Activity Health Meeting Toolkit and other resources may be found on the Center for Science in the Public Interest website: http://cspinet.org/nutritionpolicy/healthy-meeting.html

Eating healthier can be very exciting, and does not mean eating is less tasty. The toolkit has sample menus and ideas. By being creative, eating healthy will be more satisfying than other food choices that often leave you hungry soon after eating and lacking energy. A healthier meeting will include food choices that leave participants with sharper minds and increased energy.

By Krista Click, Director Food Protection Program, ISDH

ISDH Food Protection Program Receives Training Grant for 2016

The ISDH Food Protection Program has received an Association of Food and Drug Officials (AFDO) grant for ISDH to hold a Food Safety Symposium in 2016. Indiana, like other states, has provided a seminar bi-yearly to provide continuity and team building with regulators and industry. Due to various cutbacks, the seminar was last held in 2008. Holding the Food Symposium is a frequent request of local health departments. It is especially needed due to the updating of the Indiana Retail Food Establishment Sanitation Requirements Rule, as well as various emerging issues, and need for skills building. The seminar is designed for state and local food specialists responsible for retail food protection in their respective jurisdictions. It will consist of local and/or national speakers and trainings. This will give state and local participants the opportunity to hear the latest retail food information directly from the experts and serve as an important networking opportunity for food staff.

The seminar will be in central Indiana and will include three tracks: Food Code, Emerging Issues and Skills Building. The sessions will address topics included in the 2013 FDA Model Food Code that may be unfamiliar to current regulators. This is a cost efficient way to train staff, discuss Indiana retail food establishment sanitation requirements and encourage consistent and meaningful risk-based inspections.

This grant will also be used to host a national food safety specialist, Dr. Brian Nummer, to conduct workshops for state and local health departments. Dr. Nummer has been an associate professor of food safety at Utah State University and a food safety consultant for the past ten years. He consults for some of the largest retail and food service companies and travels around the country to conduct workshops in areas such as fermentation, Reduced Oxygen Packing (ROP), Good Manufacturing Practices (GMPs), Hazard Analysis and Risk-Based Preventive Controls for Human Food (HARPC). Training offered by Dr. Nummer

will include coverage in detail of FDA Model Food Code sections 3-502.11 Variance Requirement, 3-502.12 Reduced Oxygen Packaging (ROP) Without a Variance Criteria, fermentation/acidified foods and other impacted code sections.

Dr. Nummer is a "Process Authority" and will provide participants with information on the set up, use and maintenance of equipment. Knowledge of specialized equipment and facilities is especially valuable when evaluating Hazard Analysis Critical Control Point (HACCP) plans.

Fermentation/acidified foods is a popular topic among Indiana artisans and entrepreneurs, and our program has received requests from local and state staff for formal training.

Two training sessions, approximately 3.5 days in length total will be provided regionally throughout Indiana, at two locations. The course will be open as slots are available to industry food safety leaders and academia. Following attendance regulatory staff will be able to share this knowledge with other regulators, the regulated community and the general public.

By Delnaaz Daruwala, VNRFRPS Coordinator, FPP ISDH

Hold These Dates

2016 Food Safety Symposium
November 15-16, 2016
(tentative date)

Dr. Brian Nummer Food Safety Specialist Trainings
(Pick one)
June 21-24, 2016
Hendricks County Government Building, rooms 4&5
Danville, IN
or
September 13-16, 2016
Welborn Conference Center
Evansville, IN

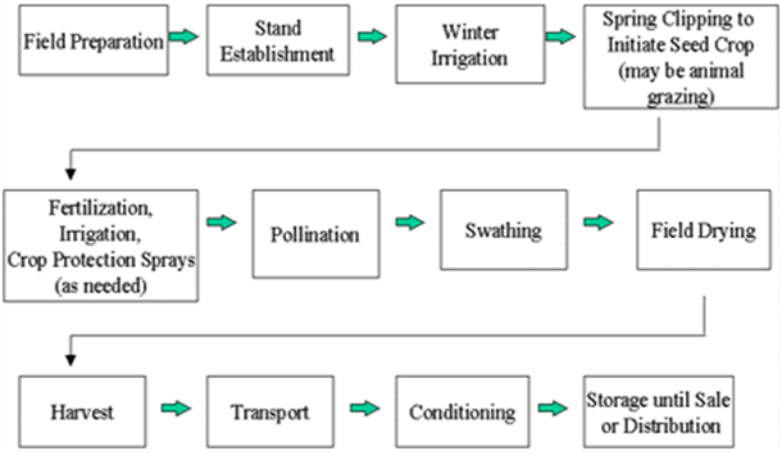
Locations and registration details will be advertised on the Food Protection webpage and through Eventbrite.

No Safe Sprouts without Safe Seeds

Since 1996, there have been at least 30 reported illness outbreaks associated with sprouts, many of which were caused by various strains of *Salmonella* and *E. coli*. Sprout seeds are frequently identified as the most likely source of the pathogens, yet it is unclear exactly how seeds become contaminated. Most alfalfa, bean, radish and clover seeds sold into commerce are used for growing agricultural crops, with only a small portion of seed going to sprout production. It is unlikely that farmers know which of their seeds are destined for sprouts until late in the production process and it is not always economically feasible or practical for farmers to produce their all seeds under conditions controlled for microbial safety.

This leaves many opportunities for contamination during growth, harvest, conditioning, storage and transportation.

Figure 1. Typical Seed Production Process



Why does it matter?

Sprouts present a unique challenge because the conditions necessary to grow them (high humidity, neutral pH, high nutrient) are conditions that also allow for the rapid proliferation of pathogenic bacteria. Even if levels of bacteria on the seeds are too low to cause illness, they can increase by a thousand fold during growth and pose a significant health risk to consumers.

To complicate things further, many studies have shown that when a contaminated seed germinates, pathogens on the seed surface can become established inside the sprout tissue. The only way to kill internalized pathogens is to apply a kill step such as cooking or irradiation. For these reasons, a multi-hurdle preventative approach focusing on good manufacturing practices, seed treatment and microbiological monitoring is recommended for safe sprout production.

Seed treatment is an intervention that can be used to reduce microbial populations on the surface of the seed prior to germination. For example, many commercial producers soak seeds in high concentrations of chlorine (2,000 - 20,000ppm) in an agitator for several minutes, followed by several plain water rinses prior to germination. The efficacy of treatments such heat, antimicrobial chemicals and irradiation varies greatly because bacteria are protected in niches of the textured seed surface. Unfortunately, there currently is no single treatment that has been shown to completely and reliably eliminate pathogens on seeds or sprouts without affecting germination, yield and appearance.

Safety starts with safe seeds, but doesn't end there. As with any other food, controls must be in place through the entire production process. Larger sprout growers subject to FDA's new produce safety rule will now be required to conduct environmental monitoring for *Listeria* and test each production batch of sprouts or spent irrigation water for *Salmonella* and *E. coli* O157:H7. Microbial testing may not be practical for smaller retail operations, but there are many other safety measures they can put in place from purchasing to shipping. All growers

should have and follow a written food safety plan that address facility design and maintenance, seed purchasing, supplier verification, receiving, storage, employee health & hygiene, cleaning and sanitizing equipment and tools, *Listeria* control and recordkeeping. For more information regarding best practices for sprout production, visit the Sprout Safety Alliance website http://www.iit.edu/ifsh/sprout_safety/ or FDA document "Growing Sprouts in Retail Food Establishment" at http://www.fda.gov.

By Jennifer Coleman,
Food Safety Farm Consultant

Defending the Dietary Guidelines

Colby Vorland M.S., Connie Weaver Ph.D., Purdue University

Recently, high profile criticisms of the U.S. Dietary Guidelines have appeared on various platforms arguing that the Dietary Guidelines are based on weak and incomplete evidence and may cause harm. Several overarching themes are apparent in many of the criticisms, which include: the Guidelines keep changing and therefore we should not regard them as science-based, they correlate with the increase in obesity and other chronic diseases and therefore cause them, and that long-term randomized trials do not exist for many dietary patterns recommended by the Guidelines. Such controversy only serves to undermine the public's trust in the development of the Guidelines in a country of dietary crisis. We address each theme below, and make a plea to be mindful of the greater public health benefit in promoting healthful habits rather than engaging in battles that derail the main messages of the Guidelines.

A Brief History of the Dietary Guidelines for Americans

Major Recommendation Changes From Previous Issue	Dietary Guidelines Issue
1980	First USDA guidelines to recommend avoidance of excessive intakes of certain food components (fat, saturated fat, cholesterol, sodium, alcohol).
1985	None.
1990	Specific limits to total fat (≤30%), saturated fat (≤10%), cholesterol (≤300mg), specific guidance for fruits and vegetables and grains (at least 3 servings vegetables, 2 servings fruits, 6 servings grains).
1995	Specific limit to sodium (≤2400mg), greater emphasis on physical activity and weight maintenance. *Now legislatively mandated to publish a report every 5 years.*
2000	Trans fat limit recommended, food safety added.
2005	Addition of recommendations for specific populations (such as a reduced sodium recommendation for hypertension (≤1500 mg/day) and a potassium target of 4700 mg/day), addition of a minimum for dietary fat (20%). Specific recommendation for half of grains as whole grains. Introduction of "discretionary calories" and "nutrients of concern". Keep trans fats as low as possible. *First issuance of a policy document based on the advisory committee's report. First use of evidence-based process.*
2015	See New Guidelines 2015-2020 http://health.gov/dietaryguidelines/2015/
References: (1, 2, 3)	

Are the Dietary Guidelines Changing?

A criticism of the Guidelines is that they are not reliable because they keep changing, so we should wait for overwhelming evidence before adopting them. Yet, they have been remarkably consistent over time, considering that nutrition science is relatively young. Food guides have been issued by the USDA since 1894, yet the release of the Dietary Guidelines in 1980 and Food Guide Pyramid in 1984 marked a shift in recommendations from a foundational diet to prevent nutrient deficiencies to promoting health requirements and preventing chronic diseases by encouraging intakes of shortfall nutrients and foods and avoiding excess of certain nutrients (1).

Since 1980, only minor shifts in recommendations have occurred. As nutritional science progresses, the foundational recommendations remain largely the same, except for an increased targeting of specific populations. The overall themes from the 1980 guidelines are still observed in the 2010 guidelines: eat a variety of foods, maintain ideal weight, avoid too much fat, saturated fat and cholesterol, eat foods with adequate starch and fiber avoid too much sugar and sodium, and drink alcohol in moderation. An emphasis on a balance of nutritious foods is sensible and evidence-based. Each iteration of the Guidelines improves the process and increases the confidence in and issuance of specific recommendations with an accumulation of research.

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Defending the Dietary Guidelines

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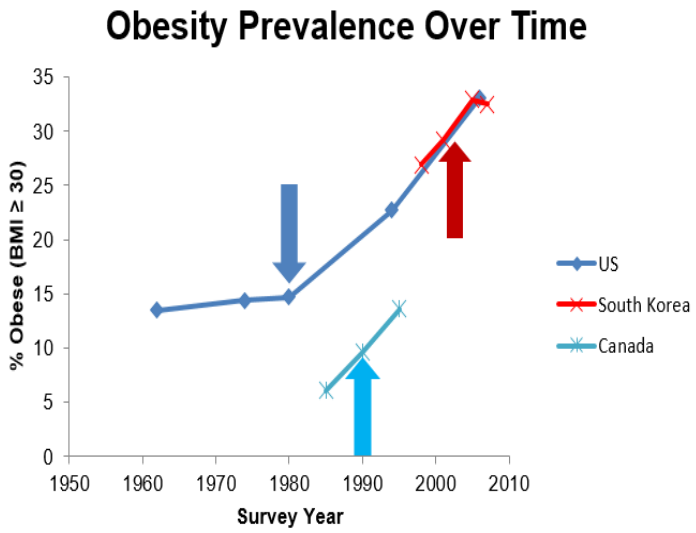
issuance of specific recommendations with an accumulation of research.

Do the Dietary Guidelines Cause Disease?

Another common criticism is that obesity and other chronic diseases have increased since the adoption of the Dietary Guidelines, suggesting to some critics that the Guidelines are harmful. Specifically cited as a cause of harm was the increase in carbohydrates from about 43% to 49% following the 1980 Guidelines recommendation that total fat not exceed 30% of calories, while the average fat intake was approximately 37% in 1976-1980 and decreased to 33% by 1999-2000 (4). However, the argument that increased carbohydrate consumption led to a worsening of obesity and related diseases fails on several fronts. For one, there was a corresponding increase in total calories driven by carbohydrates (5), so that fat consumed remained stable over the time period even though the proportion of fat declined (6). In the early 1900s, food availability data suggested that the carbohydrate to fat ratio was higher than it is now (7), yet this did not drive obesity. It is far more likely that other rapid changes in the food supply independent of the changes suggested by the Guidelines, including an increased overall food availability, contribute to the rise in obesity (5).

A temporal line of evidence that precludes the Guidelines as a direct contributor to obesity is the rise in obesity in other countries that adopted similar dietary recommendations at different times. For example, Canada released official recommendations to lower fat intake in 1990 (Canada's Food Guide to Healthy Eating) calling for no more than 30% dietary fat for the first time (8). Yet, obesity was clearly on the rise in Canada prior to these guidelines (9). South Korea released its first quantitative guidelines in 2003 (10) recommending only 20% dietary fat (11), yet obesity was already increasing rapidly, despite dietary fat consumption increasing and carbohydrate decreasing steadily (12). China's recent economic growth also caused a reduction in carbohydrate and increase in dietary fat that parallels the increase in obesity (13, 14). National guidelines are exceedingly unlikely to cause disease; it is far more likely that countries tend to adopt dietary recommendations that provide specific limits when they reach a point when chronic diseases outweigh nutritional deficiencies.



Arrows represent when the country adopted its first official Dietary Guidelines or provided a quantitative recommendation on dietary fat. National survey data sources: WHO, Kim et al (2014), Katzmarzyk et al (2006). U.S. ages 20-74, South Korea ages ≥ 19, Canada various (age adjusted).

Why don't the Dietary Guidelines decrease chronic diseases like obesity?

Adherence to the Guidelines would have to be high to have any impact on chronic diseases. A recent systematic review of 25 studies (15) that addressed adherence to U.S. Guidelines found that adherence to all Food Guide Pyramid (1992-2005) recommendations were reported to be between 0% and 6% of participants. The authors noted that there is no evidence that adherence to Guidelines has improved over time.

A look at what types of foods Americans are actually eating reveals how backward our consumption patterns are. According to an analysis of NHANES 2009-2010 for the Dietary of NHANES 2009-2010 for the Dietary Guidelines 2015 Scientific Report (16), the top 3 food categories that provide about 29% of calories in the American diet are burgers and sandwiches, desserts and sweet snacks, and sugar-sweetened beverages. These foods fall into categories recommended to be minimized by the Guidelines, yet they contribute to almost ⅓ of energy. Analysis for the 2010 report found that "grain-based desserts" were the top source of calories for children and adolescents and adults (17). Non-adherence to recommendations is not a problem unique to the U.S. Among 113 countries in a recent analysis, only 0.4% meet the recommendation for vegetables from the 2010 U.S. Dietary Guidelines, 7.6% for whole grains and 4.4% for seafood (18).

Dietary Guideline adherence is associated with improved health.

Studies that compare people who adhere more closely to the Guidelines vs. those who do not find that adherence is associated with a reduced risk in several chronic diseases.

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Defending the Dietary Guidelines

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A recent meta-analysis of 15 cohorts (19) indicates that high adherence to guidelines is associated with a reduction in all-cause mortality, cardiovascular disease, and diabetes by 22% each, and cancer by 15%. Because such adherence can predict these risk reduction associations, this greatly increases our confidence in the Guidelines as a whole. With adherence to government recommendations already extremely low, it is imperative that faulty arguments against them are dismissed so that the public doesn't lose trust that following the Guidelines will improve health.

Is the Evidence Behind the Dietary Guidelines Weak?

A final criticism of the Guidelines is that long-term randomized controlled trials don't exist to inform many of the recommendations. Nutrition science, unlike other medical interventions, has the inherent difficulty of assessing the relationship of foods and nutrients with outcomes that are a consequence of inadequate intake or overconsumption. Ethical considerations prohibit restriction of essential nutrients or consumption of toxic levels of nutrients for prolonged periods (20). A small dietary change in macronutrients must usually be substituted with another, such as exchanging dietary carbohydrate for fat, which tends to change other nutrients and bioactives that are not being tested making it difficult to definitively tease apart the role of the substitution. Practical considerations such as cost and adherence make it difficult to undertake long-term trials on many dietary questions. For example, the diet modification wing of the $625 million Women's Health Initiative trial failed to hit a target goal of 20% dietary fat, only achieving 29% with an intensive behavioral modification program for each participant (21). This leaves a definitive answer to the original research question in doubt. Short-term studies that provide controlled foods to participants and measure validated surrogates are an attractive alternative option. Observational studies, with inherent limitations to causal inference, can identify groups who already achieve desired eating patterns and look at hard outcomes like mortality. Ultimately, a conciliation of evidence from different research designs interpreted in a biological context allows for population-based recommendations to be made.

Nevertheless, large randomized controlled trials do exist that inform the guidelines, such as PREDIMED, DASH and OmniHeart. Moreover, the complete assessment of these, smaller trials and observational studies are systematically evaluated, graded and synthesized in a transparent process that can be followed at nel.gov. In addition to these reviews, food pattern modeling is used extensively to form realistic Guidelines that meet or limit nutrient and food goals set by the IOM and the dietary guidelines review process. Based on such modeling, recent Guidelines provide new dietary patterns that adhere to recommendations, including a Vegetarian and Mediterranean-style. Criticisms of the Guidelines usually propose alternative eating patterns that do not meet a sufficient level of evidence to inform population recommendations. This does not necessarily preclude individualization of such patterns or more specific recommendations by dietitians or physicians to subpopulations that may benefit.

Some propose that, because of less than perfect evidence, we abandon the Guidelines. The consequences of this would be dire. With a lack of formal Guidelines, countless local, state and national organizations responsible for educating and feeding millions of Americans would need to spend resources determining what is best for their constituents, or worse, may disregard health as a goal for food delivery. Now, School Meals Programs are developed based on recommendations from the Guidelines, WIC provides food packages that align with the Guidelines, and SNAP sets food stamp allotments based on the Guidelines. These three programs alone provide meals and education to tens of millions of Americans. The current Dietary Guidelines development process, in which willing scientists of diverse perspectives at the top of their field are nominated and thoroughly vetted and systematically synthesize the best evidence, is unquestionably a better option than nothing.

Conclusion

There are many strategies for researchers to participate in the dialogue for improving the evidence base available to committees that are making public health recommendations and to provide input into the process without going directly to the public. These avenues include publications in scientific journals, working through professional societies, and responding to requests and opportunities announced in the Federal Register. The public benefits most from the cumulative synthesis of a process by a panel of experts who distill the current evidence into public health guidance targeted specifically toward the consumer.

Subsequent iterations of the Dietary Guidelines will evolve with a growing evidence-base and changing population needs. It is unlikely that all details in the current iteration will stand the test of time as the definitive dietary guidance. But that doesn't mean the overall themes are not appropriate and that the Guidelines can greatly improve the health of Americans who follow them. Current critiques of the Guidelines fail to provide convincing arguments otherwise. The consistency of these themes with recommendations from other scientific associations, other countries, and over time is compelling. The evidence of benefit in those who adhere more closely to recommended eating patterns is also substantial. Public criticism without thoroughly addressing the detailed systematic reviews that inform the

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Dietary Guidelines

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Guidelines undermines the public's confidence in them and further risks the health of a population that already fails to follow dietary recommendations.

About the Authors

Colby Vorland M.S., is a graduate student at Purdue

Connie Weaver Ph.D., is distinguished Professor and Head of the Department of Food and Nutrition at Purdue University, West Lafayette, IN. In 2000, she also became Director of a National Institutes of Health funded Botanical Center to study dietary supplements containing polyphenolics for age-related diseases. Her research interests includes mineral bioavailability, calcium metabolism and bone health. She was a member of the National Academy of Sciences Food and Nutrition Board Panel to develop the new recommendation for calcium and related minerals. She has numerous national awards. In 2005 Dr. Weaver was appointed to the 2005 US Dietary Guidelines Advisory Committee.

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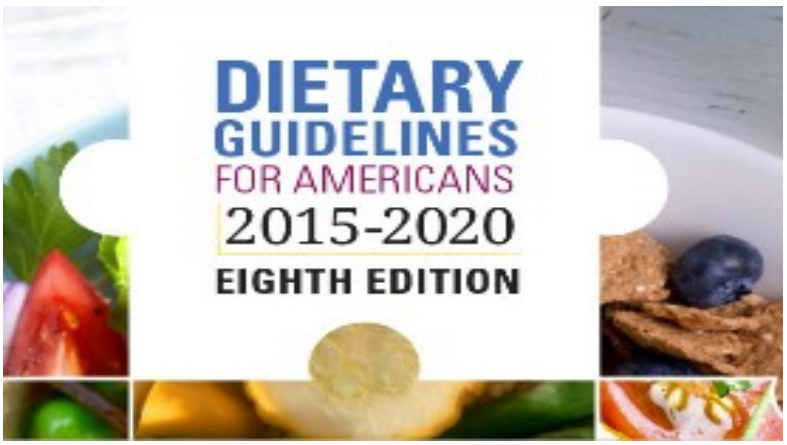

Special thanks to Colby and Connie for providing this detailed analysis of the Dietary Guidelines and issues surrounding them. The decisions concerning guidelines affect food protection through labeling, standards, approved sources, new foods from farm to fork and allergens as well as protecting the health of all citizens.

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Tidbits

New Guidance Document Online

Indiana Public Schools and ISDH Food Protection collaborated to create guidelines for schools for sharing tables and food recovery. Now there is a guidance document to assist local health departments in implementing the guidelines.

Guidance on Schools and Other Facilities Implementing "Sharing Tables" and "Food Recovery" Programs Recommended by USDA is found at: http://www.in.gov/isdh/files/School_Sharing_Tables_and_Food_Recovery_12-23-2015_(2).pdf

North-East Field Position Filled

Sharon Pattee has accepted the north-east field staff position. Welcome! Sharon can be reached at 317-719-5453 or e-mail spattee@isdh.in.gov .

South-West Field Position Filled

David Schmidt

Food Protection is pleased to announce that David Schmidt has chosen to returned to his previous position as Field Specialist for the Food Protection Program. David worked out of Evansville for a little over 4 years. David expressed that enjoying the job is key to a fulfilling career. He added that he has a passion for regulatory work and enjoys his co-workers. David can be reached at 317-412-2119 or e-mail dschmidt2@isdh.in.gov

Comings and Goings

There has been a change in ISDH CodePal Technical Staff contacts. Irene Jameson is now supporting other ISDH program areas. Phyllis Simpson remains the main CodePal contact and Eli Shebanov and their supervisor, Mohan Ambaty, are also available.

ISDH CodePal Technical Staff

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Opening

Andrew Miller, Food Specialist resigned in January 2016. Andrew first came to ISDH as Food Defense Coordinator, organized many IFTAPs and was a Wholesale Inspector.