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Food and Drug Law Institute

Food and Dietary Supplement Safety and
Regulation Conference

Technology and Innovation: Can it Improve Both
Food Safety and Food Access?

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Of Counsel

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Foodborne Diseases - USA

- In 2018, the U.S. Centers for Disease Control (CDC) identified 25,606 cases of foodborne illness infections, 5,893 hospitalizations, and 120 deaths. Incidences of infections in 2018 increased significantly for *Cyclospora*, *Vibrio*, *Yersinia*, STEC, *Campylobacter*, and *Salmonella*.
- <https://www.cdc.gov/foodsafety/outbreaks/multi-state-outbreaks/outbreaks-list.html>.

Pathogen Case Counts – 2019

Number of laboratory-diagnosed bacterial and parasitic infections, hospitalizations, deaths, incidence rate, by pathogen — FoodNet*

Pathogen	Infections	Hospitalizations		Deaths		Outbreak-associated		International travel-associated		Incidence rate [†]
		n	%	n	%	n	%	n	%	
Bacteria										
<i>Campylobacter</i>	9,799	2,043	20.8%	29	0.3%	20	0.2%	1,570	16.0%	19.61
<i>Listeria</i>	135	132	97.8%	21	15.6%	3	2.2%	6	4.4%	0.27
<i>Salmonella</i>	8,596	2,492	29.0%	54	0.6%	551	6.4%	965	11.2%	17.20
<i>Shigella</i>	2,428	661	27.2%	3	0.1%	76	3.1%	615	25.3%	4.86
STEC	3,144	667	21.2%	10	0.3%	265	8.4%	634	20.2%	6.29
<i>Vibrio</i>	481	137	28.5%	13	2.7%	24	5.0%	50	10.4%	0.96
<i>Yersinia</i>	681	146	21.4%	4	0.6%	0	0.0%	37	5.4%	1.36
Parasite										
<i>Cyclospora</i>	758	38	5.0%	0	0.0%	239	31.5%	110	14.5%	1.52
Total	26,022	6,316	24.3%	134	0.5%	1,178	4.5%	3,987	15.3%	—

Abbreviations: STEC = Shiga toxin-producing *Escherichia coli*

* Data collected in Connecticut, Georgia, Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York

† Per 100,000 persons

Foodborne Diseases - USA

CDC's FoodNet Fast provides online access to information reported to the [Foodborne Diseases Active Surveillance Network \(FoodNet\)](#).

Note that FoodNet's [surveillance area](#) includes only approximately 15% of the U.S. population.

<https://www.cdc.gov/foodnet/foodnet-fast.html>

Foodborne Disease Outbreaks - USA

FDA is currently investigating a *Salmonella* outbreak involving over 60 affected individuals.

As of the date of the last update, March 10, the source of the contamination has not been identified

Foodborne Disease Outbreaks - USA

FDA determined that a *Salmonella typhimurium* outbreak between June and August of 2021 caused at least 31 reported illnesses and four hospitalizations. This outbreak was linked through epidemiology and traceback to packaged salad greens and was notable in that it is believed to be FDA's first domestic investigation of a foodborne illness outbreak associated with leafy greens grown in a Controlled Environment Agriculture (CEA) operation.

The CEA operation at issue produces leafy greens using common commercial high density hydroponic growing techniques with deep water culture and floating raft production methods.

https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-report-highlighting-salmonella-outbreak-packaged-leafy-greens-produced-controlled?utm_medium=email&utm_source=rasa_io

Foodborne Disease Outbreaks

FDA and CDC investigated a multi-state outbreak of *E. coli* O157:H7 infections linked to packaged salads. As of March 2022, the investigation had identified ten individuals from 4 states infected with the outbreak strain of *E. coli* O157:H7. Affected individuals ranged in age from 26 to 79 years; four had been hospitalized; and one developed kidney failure (hemolytic uremic syndrome (HUS)).

The investigation determined that seven of the affected individuals had purchased packaged salads marketed as Nature's Basket Power Greens or Simple Truth Organic Power Greens at grocery stores before becoming sick. Leafy greens used in the identified products were sourced from Salinas and Imperial Valley, California, and Yuma, Arizona.

<https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o157h7-power-greens-packaged-salad-january-2022>

Foodborne Disease Outbreaks - USA

Up to date information on FDA investigations of foodborne outbreaks may be obtained at:

<https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks>

Regulatory Actions to Promote Food Safety

Food Traceability was a key component of the 2010 [Food Safety Modernization Act](#) (FSMA). On September 23, 2020, FDA published a proposed rule to establish additional traceability recordkeeping requirements for companies that manufacture, process, pack, or hold certain foods listed on a newly formulated proposed Food Traceability List (FTL). (85 Fed. Reg. 59984). FDA's proposed rule would require companies that "manufacture, process, pack, or hold foods on the FTL" to establish and maintain records containing Key Data Elements (KDEs) associated with different Critical Tracking Events (CTEs).

The purpose of the proposed KDE and CTE recordkeeping requirements for foods identified as "high risk" on the FTL is to enable rapid FDA action to identify recipients of potentially adulterated or misbranded foods.

Regulatory Actions to Promote Food Safety

On November 5, 2020, and January 12, 2021, FDA made available additional resources to assist public understanding of the proposed rule. Included in the additional resources are (1) a tool that enabled better understanding of the model that was used to develop the Food Traceability List; (2) a recorded webinar that explained the development and intended benefits of the proposed rule; (3) reference documents that provide additional information on the proposed rule; and (4) a Frequently Asked Questions document that FDA prepared based on questions that it received after the initial publication of the proposed rule.

Regulatory Actions to Promote Food Safety

Although clearly justified in terms of the societal impacts of foodborne illnesses, the traceability requirements will not come without cost.

‘It’s going to be difficult for a lot of operations, particularly small-to-midsize harvesters and distributors. Keeping track of everything is painful right now and it’s going to get more painful and there are some companies that aren’t going to be able to make that transition and, if FDA enforces these requirements, it could mean fines, lawsuits or even being shut down.’

Regulatory Actions to Promote Food Safety

Recognizing the burden that food traceability requirements could have for producers, distributors, and consumers, in June 2021, FDA initiated a challenge for the development of low-cost food traceability components, i.e., software, hardware, and analytics capabilities that could be incorporated in functioning food traceability platforms.

On September 13, FDA announced 12 winners of the Low-or No-Cost Food Traceability Challenge.

<https://www.fda.gov/food/new-era-smarter-food-safety>

Regulatory Actions to Promote Food Safety

On February 16, 2022, USDA's Food Safety and Inspection Service (FSIS) published a proposed rule setting forth actions intended to address *Salmonella* in meat products. Specifically, FSIS proposed pathogen reduction performance standards for *Salmonella* in raw comminuted pork and raw intact or non-intact pork cuts.

FSIS also announced its intended procedures for assessing whether establishments producing these products are effectively addressing *Salmonella*.

The notice also provides a brief summary of FSIS's recent announcements regarding *Salmonella* in poultry products.

The comment period for the proposed rule ends on
87 Fed. Reg. 8774 (Feb. 16, 2022)

Regulatory Actions to Promote Food Safety

On March 23, 2002, USDA amended the list of substances allowed for use in organic production to include potassium hypochlorite for use as a sanitizer for cleaning irrigation equipment and treating irrigation water.

USDA AMS added potassium hypochlorite to the list of substances allowed in organic production to provide organic farmers an additional tool for treating irrigation water and cleaning irrigation equipment.

87 Fed. Reg. 16371 (Mar. 23, 2022)

Traceability and Right to Know

In addition to the need for functional food traceability to address food safety issues, there is also a powerful “right to know” aspect to food traceability. Many consumers want to know where their food comes from, whether it was grown or produced “sustainably,” and that it was legally sourced (for example with lawful fishing practices). Concomitantly, many retailers want to be able to accurately and reliably represent to their consumers where and how the food that they sell is sourced.

<https://www.ibm.com/blockchain/solutions/food-trust> .

Questions?



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