

SESSION 2

KEEP IT LEGAL

Review of the Upcoming Regulatory Tidal Wave



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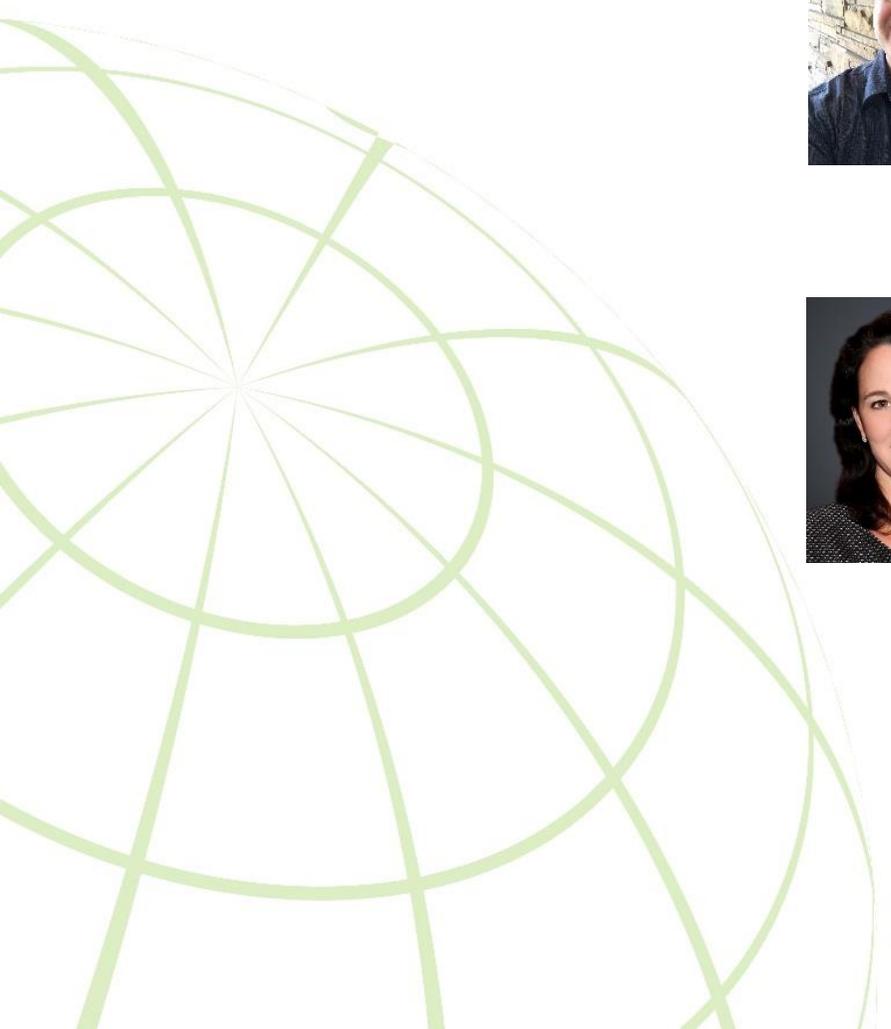
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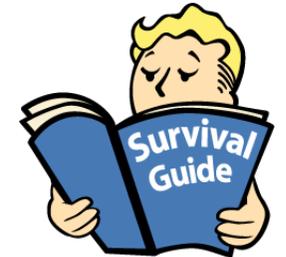
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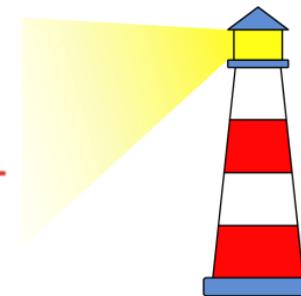
Tips to Survive the Regulatory Tidal Wave

Automated Commercial Environment

- U.S. Customs and Border Protection
<http://www.cbp.gov/trade/automated>
- Participating Government Agencies PGA List
<http://www.cbp.gov/document/guidance/ace-november-1-pga-forms>
- Centers for Excellence and Expertise Directory
<http://www.cbp.gov/trade/centers-excellence-and-expertise-information/cee-directory>



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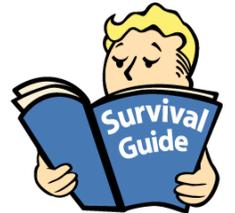


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Tips to Survive the Regulatory Tidal Wave

SOLAS – Container Weight Verification



- International Maritime Organization
<http://www.imo.org/en/OurWork/Safety/Cargoes/Containers/Pages/Verification-of-the-gross-mass.aspx>
- World Shipping Council
<http://www.worldshipping.org/industry-issues/safety/cargo-weight>
- Frequently Asked Questions
<http://www.worldshipping.org/industry-issues/safety/faqs>
<http://www.ttclub.com/loss-prevention/publications/container-weighing/>
<http://ichca.com/container-weighing>



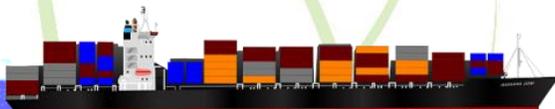
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INNOVATION | LOGISTICS



Food Safety Modernization Act

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Rationale for FSMA

- Modernize our food safety system in the US
- Prevention vs. Reaction
- Mandates FDA to set new standards and make sure these standards are met in US and for importers
- Mandatory recall authority and ability to stop shipments of “suspect” food

FSMA Key Areas

- **Preventive controls** - comprehensive, prevention-based across the food supply
- **Inspection and Compliance** - The legislation recognizes inspection is important to hold the industry accountable. FDA will apply inspection resources in a risk-based manner with innovative approaches.
- **Imported Food Safety** - FDA has new tools to ensure that imported foods meet U.S. standards and are safe. For the first time, importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety, and FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards.
- **Response** - For the first time, FDA has mandatory recall authority for all food products. New authorities that are also in effect: expanded administrative detention of products that are potentially in violation of the law, and suspension of a food facility's registration.
- **Enhanced Partnerships** - strengthening existing collaboration among all food safety agencies—U.S. federal, state, local, territorial, tribal and foreign entities

Final Rules

- “Preventive Controls” for Human Food
- “Preventive Controls” for Animal Food
- The “Produce Safety Rule”
- Accredited Third-party Certification
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
- Sanitary Transportation of Human and Animal Food
- Protect Against Intentional Adulteration Rule (*proposed*)

Types of Companies

- Production (farm) vs. preventive controls
- Manufacture, pack, label, or hold food – must be registered facility
- Shippers, receivers, and carriers who transport food in the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce.
- Also apply to a person outside of the United States, such as an exporter, who ships food to the United States in an international freight container by ocean-going vessel or in an air freight container, and arranges for the transfer of the intact container in the United States onto a motor vehicle or rail vehicle for transportation in U.S. commerce, if that food will be consumed or distributed in the United States.

Compliance Calendar

Rule	2015	2016	2017	2018	2019	2020	2021	2022
Produce Safety	Effective Date	Jan	Large	Jan.	Ag. Water	Jan.		
			Small		Jan.	Ag. Water	Jan.	
			V. Small			Jan.	Ag. Water	Jan.
Preventive Controls Human	Effective Date	Sept	Large					
			Small	Sept				
			V. Small		Sept			
Preventive Controls Animal*	Effective Date	Sept	Large	PC				
			Small	GMP	PC			
			V. Small		GMP	PC		
FSVP	Effective Date	Jan	6 mo. after compliance date for supplier					

Effective Date
 Large
 Small
 V. Small
 Ag. Water

*Animal Food rule has 1-yr staggered compliance dates for GMPs and preventive controls

Rule	2015	2016		2017	2018	2019
	Oct	Apr	May			
Intentional Adulteration			Final	Large ?		
				Small	Small ?	
				V. Small	V. Small	V. Small ?
Sanitary Transportation		Final	Large June			
			Small June		Small June	
3 rd Party Cert.	Final					

Final
 Large
 Small
 V. Small

Challenges

- ❑ Hazard Analysis (“assess the probability that these hazards will occur in the absence of controls”)
- ❑ FSVP is difficult and compliance costs are significant
- ❑ Established food safety programs and requires collaboration between parties
- ❑ Get started for Sanitary Transport Act compliance; Implications from 2005:
 - ❖ **Vehicles and Transportation Equipment, Transportation Operations** –such as having established procedures for the exchange of information about temperature control, between the shipper, carrier and receiver
 - ❖ **Documentation and Records**
 - ✓ **Training:** Training of carrier personnel in sanitary transportation practices and documentation of the training.
 - ✓ **Records:** Maintenance of written procedures and records by carriers and shippers related to transportation equipment cleaning, prior cargos, and temperature control.

Resources

- <http://www.fda.gov/fsma>
- Guidance, Fact Sheets, Presentations, recorded Webinars
- Submit questions to Food Safety Technical Assistance Network
- Online course will be developed and posted for training
- FDA Webinar for Sanitary Transport Rule: April 25th at 11amEST
- *Food Logistics* magazine articles
- Association sponsored FSMA Workshops – GMA, United Fresh, PMA, etc.