





TECHNICAL SEMINAR

MAKING THE DIFFERENCE
LAST STEPS TO FOOD SAFETY
MODERNIZATION ACT (FSMA)
COMPLIANCE: ANNOUNCEMENT
OF ACCREDITATION BODY AND
CERTIFICATION BODY

Ho Chi Minh City, 29 March 2019

SGS

DETAILED PROGRAM

8:00 - 08:30	Welcome delegates	
8:30 - 08:45	Opening speech Representative of SGS Viet Nam	
08:45 – 09:45	Topic 1: Updated information from Accreditation Body and Certification Body in FSMA certification activities Mr. Hank Karayan – Global FSMA Program Director (via Skype) Mr. Truong Hoang Lac – FSMA Auditor and Trainer – SGS Viet Nam	
9:45 – 10:10	Q&A	
10:00 – 10:20	Tea break	
10:20 – 11:05	Topic 2: Global Integration, the U.S. Food Safety Modernization Act (FSMA), and Impact on Vietnam's Food Safety System Mr. Herb Cochran – Senior Advisor trade facilitation – AmCham Viet Nam	
11:05 – 11:30	Topic 3: FSMA and food quality assurance issues Mr. Lam Van Xu – AFL Food Lab Manager – SGS Viet Nam	

11:30 – 11:45 Q&A





UPDATED INFORMATION FROM ACCREDITATION BODY AND CERTIFICATION BODY IN FSMA CERTIFICATION ACTIVITIES

Mr. Hank Karayan – Global FSMA Program Director (via Skype)

Mr. Truong Hoang Lac - FSMA Auditor and Trainer - SGS Viet Nam



FSMA CERTIFICATION



Hank Karayan

Global FSMA Program Director

WHEN YOU NEED TO BE SURE





- The FDA Food Safety Modernization Act (FSMA) is a US law
- The most sweeping reform of US food safety laws in more than 70 years
- Signed into law by President Obama on January 4, 2011
- Aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it
- Enables FDA to better protect public health by strengthening the food safety system



FDA published <u>seven</u> foundational Rules for FSMA compliance



MAIN ASIA-PACIFIC COUNTRIES & PRODUCT GROUPS - EXPORTS TO US (IN '000 USD)

Rank	Country						Vegetables & Prep.		Dairy &	Grand Total (Thousands)
4	Vietnam	1,392,347	1,259,003	937,076	84,450	32,921	26,901	13,848	186	3,746,732

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FSMA RULES & THEIR APPLICABILITY

7 Rules of FSMA	Manufacture, Processing, Dist'n Centers & Warehouses - Human Food	Manufacture, Processing, Dist'n Centers & Warehouses - Animal Food		Processing, US Dist'n Centers & Warehouses Foo		US Importers of Human & Animal Food	1 4	oduce rms	US Shippers, Carriers, Receivers of Human & Animal Food
Preventive Controls for Human Food (PCHF)	Х								
Preventive Controls for Animal Food (PCAF)		Х							
Foreign Supplier Verification Program FSVP				X					
Produce Safety						X			
Sanitary Transportation (US)							X		
Intentional Adulteration (Food Defense)	Х								
Third Party Accredited Certification rule (voluntary)	Х	Х		For VQIP		Х			

Source: FDA

4



- VQIP (Voluntary Qualified Importer Program) is available to US importers, allows expedited entry of food to the US
- Reduced delays at the border
- Exam/sampling would generally be limited to "for cause" situations
- Allows customers to receive their products sooner
- Confidence in the importer's food safety measures
- Commercial considerations (first-to-market, reputation, etc.)

SGS

SGS ACCREDITATION FOR FSMA CERTIFICATION

- SGS is accredited by ANSI for two programs:
 - FSMA VQIP
 - FSMA FSVP
- Scopes:
 - PC Human Food (21 CFR part 117)
 - Juice HACCP (21 CFR part 120)
 - Seafood HACCP (21 CFR part 123)
 - + over 20 sub-scopes (secondary regulations)
- SGS is on the list of accredited CBs on the US FDA website:

https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm618978.htm



FSMA VQIP CERTIFICATION

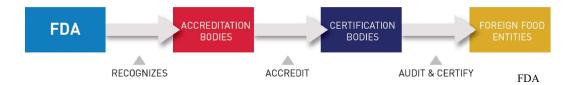


7



HOW DOES VQIP CERTIFICATION WORK?





- Accreditation bodies apply for FDA recognition
 - CB applies to recognized AB for accreditation
 - Foreign suppliers apply to CB for certification

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FSMA VQIP CERTIFICATION



- Covered by FSMA Accredited Third party certification (TPA) rule
- Foreign Supplier VQIP Certification is a prerequisite for VQIP eligibility
- VQIP Certification may also be used when mandated by FDA for certain food facilities in specific countries or supplier sites based on FDA's risk evaluation
- VQIP is applicable to all food categories regulated by FDA, including categories that are not covered by the Preventive Controls rules, such as seafood, juices, etc.
- Certificate can be granted following an unannounced regulatory audit
- VQIP certificates are renewed annually

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FSMA VQIP AUDIT STAGES



Consultative Audit :

- Unannounced audit to determine if the facility is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices
- The results of which are for internal purposes only
- Conducted in preparation for a regulatory audit
- Regulatory Audit: Unannounced food safety audit of an eligible entity to determine whether such entity is in compliance with applicable food safety requirements and the results of which are used in determining eligibility for certification.



CB RESPONSIBILITIES – VQIP AUDITS (THIRD PARTY ACCREDITED CERTIFICATION RULE)



- Ensure auditors are competent and objective
- Verify the effectiveness of facilities' corrective actions to address identified deficiencies
- Assess and correct any problems in their own performance
- Maintain and provide FDA access to certain records
- Perform facility audits unannounced
- Notify FDA on discovering a condition that could cause or contribute to a serious risk to public health
- Submit regulatory audit reports to FDA
- Maintain consultative audit reports in records

11

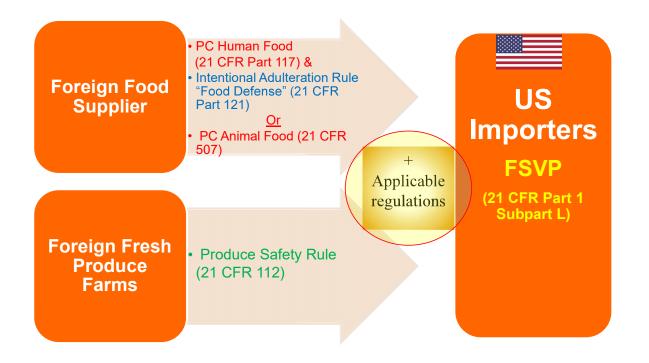


FSMA FSVP CERTIFICATION





FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP) – HOW IT WORKS





WHAT IS EXPECTED FROM US IMPORTERS?

- To provide adequate assurances that:
 - Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety provisions
 - Food is not adulterated or misbranded (as to allergen labeling)
- Share responsibility for ensuring safety of imported food
- Perform risk-based verification according to
 - Types of hazards
 - Who controls the hazards
 - Supplier performance

14



SUPPLIER VERIFICATION ACTIVITIES



- Include:
 - Onsite audits
 - Sampling and testing of food
 - Review of the foreign supplier's relevant food safety records
 - Other appropriate supplier verification activities
- A verification activity can be performed by a 3rd party



SGS <u>FSMA FSVP</u> certification is for 3rd party Supplier Verification

15



FSMA FSVP CERTIFICATION



- FSMA FSVP is a certification program similar to FSMA VQIP, but specifically designed for importers and suppliers to help them comply with the requirements of the Foreign Supplier Verification program (FSVP) but NOT VQIP.
- FSMA FSVP certification is for foreign suppliers to demonstrate to their US clients that SGS has verified their system for the purpose of compliance with FSVP



FSMA FSVP AUDIT STAGES



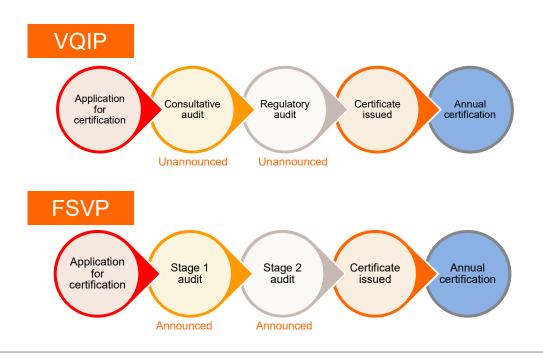
- FSMA FSVP certification is like other 3rd party certification programs. It is done is two stages:
 - Stage 1: Document review, can be offsite or onsite
 - Stage 2: Implementation audit (onsite)
- FSMA FSVP audits are announced
- SGS will issue an accredited SGS FSVP certification upon successful completion of the stage 2 audit.



VQIP VS. FSVP CERTIFICATION

VQIP CERTIFICATION	FSVP CERTIFICATION	
Applies only to facilities outside USAudit is for regulatory complianceCertificate is valid for 1 year	Applies only to facilities outside USAudit is for regulatory complianceCertificate is valid for 1 year	Similarities
		1
 Accredited by AB, regulated by FDA FSMA Accredited 3rd Party Certification Rule Is a prerequisite to apply for VQIP (expedited entry program) Regulatory (certification) audit findings must be closed out & audit report submitted to FDA within 45 days Consultative + regulatory is therefore required for initial certification Audits are unannounced Auditor cannot visit the same facility for 13 months VQIP certified facility can be entitled to FSVP certificate for the same scope 	Accredited by AB, not regulated by FDA's Accredited 3rd Party Certification Rule Is not a prerequisite for VQIP (expedited entry program) No audit report submitted to FDA Stage 1 + Stage 2 audits required for certification Audits are announced The 13-month rule does not apply, and the same auditor can go back to audit the facility FSVP certificate does not entitle the facility to VQIP certificate	Differences





SGS

WHAT DO WE AUDIT AGAINST?

Primary (overarching) regulations

- PC Human Food
- Juice HACCP
- Seafood HACCP

Secondary (product-specific regulations)

- Frozen Desserts
- Bakery Products
- Cereal flours and related products
- Macaroni and noodle products
- Fruit butters, jellies, preserves
- Fruit pies
- Frozen vegetables

- Cacao Products
- Tree nut and peanut products
- Margarine
- Sweeteners and table syrups
- Food dressing and flavorings

- Bakery products
- Beverages
- Cereal flours and related products
- Macaroni and noodle products

■ General regulations: Facility registration, Labeling, 21 CFR 100, 130, etc...

20

19



EXAMPLE: MACARONI & NOODLES

Primary (overarching) regulation:

■ 21 CFR part 117 (Preventive Controls for Human Food)

Main Scope

Secondary (product-specific) Regulations

21 CFR part 139 (Macaroni & noodle products)

General applicable regulations:

- Subpart H: Facility Registration
- 21 CFR part 11: Electronic Records and Signatures
- 21 CFR parts 100 (General), 101 (Food labeling), 130 (Food Standards General), etc.
- 21 CFR part 172 (additives)
- 21 CFR parts 182, 184, 186 (GRAS)
- 21 CFR part 189 (Substances prohibited in human food)

Sub-scopes

21



_ STEPS TO CERTIFICATION





BENEFITS OF FSMA CERTIFICATION

- The only certification for FSMA compliance
- A commercial advantage for foreign suppliers exporting to the US
- A prerequisite for expedited entry of food to the US → Advantageous for suppliers and importers
- Marketing and brand recognition
- Proof of compliance = Less audit requests from US clients

23



SGS FSMA SERVICES

Audits & Certification

- Accredited FSMA certification audit
- 2nd party supplier audit based on client requirements
- FDA GMP Audits / FSMA Desktop Review / Gap audits

Testing

- Environmental Monitoring validation
- · Micro & chemical testing
- · Allergen testing
- · Water testing

Compliance Services

- · Importer/manufacturer support supply chain risk assessment (FSVP, PCHF, PCAF)
- · Allergen Labeling
- · Marketability assessments and other customized FSMA studies/services
- · Review of Environmental Monitoring protocols (EMP)
- Product sampling/testing methodologies (MRLs, etc.)

Training

- FSPCA FSVP & PCQI (Preventive Controls Qualified Individual) Human food & Animal food
- FSMA Integration Courses
- Auditor courses, virtual training, etc.

www.sgs.com/fsma

www.sgs.com/fsma



WHEN YOU NEED TO BE SURE SGS

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GLOBAL INTEGRATION, THE U.S. FOOD SAFETY MODERNIZATION ACT (FSMA), AND IMPACT ON VIETNAM'S FOOD SAFETY SYSTEM

Mr. Herb Cochran – Senior Advisor trade facilitation – AmCham Viet Nam



Global Integration, FSMA, Vietnam

Mar 29, 2019

- Herb Cochran
 - Cố vấn cấp cao
- Tạo thuận lợi thương mại

Global Integration of U.S. Food Market

U.S. imports as a % of total U.S.consumption (2018)

fresh vegetables 32% fresh fruit 55% Preserved fruit, vegetables 27%

Seafood 94%

Countries and territories 200+

Food facilities + farms ~125,000

Import shipments

2002
 2010
 2015
 2018
 4.4 million
 8.6 million
 12.0 million
 12.2 million

2018 13.8 million 2019 (est.) 14.6 million

2025 (est.) 20.5 million

2



Public Health Burden

Foodborne diseases – U.S (annual) – FDA (2011)

affect 48,000,000 (1 out of 6)

hospitalize 128,000 deaths 3,000

Foodborne diseases - Global (annual) - WHO

affect 600,000,000

Hospitalize ...? n/a
Deaths 420,000

3

U.S. Food Safety Laws Brief History AmCham Vietnam Ho Chi Minh City Chapter

1641 Massachusetts Meat and Fish Inspection Law

1906 Pure Food and Drug Act, Meat Inspection Act1938 Pure Food, Drug, and Cosmetics Act2011 Food Safety Modernization Act

FSMA – Enhanced Partnerships AmCham Vietnam Ho Chi Minh City Chapt

Domestic U.S. capacity building. FDA must develop and implement strategies to enhance food safety and defense capacities of State and local agencies. The FSMA gives FDA a new multi-year grant mechanism for investment in State capacity to more efficiently achieve national food safety goals.

Foreign capacity building. FSMA directs FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries. One component of the plan is training of foreign governments and food producers on U.S. food safety requirements.

Reliance on inspections by other agencies: FDA is authorized to rely on inspections of other Federal, State and local agencies to meet its increased inspection mandate for domestic facilities. The FSMA also allows FDA to enter into interagency agreements with respect to the inspection of seafood facilities, both domestic and foreign, as well as seafood imports.

5

FSMA - IFSS/PFP



1913 The formation of the Federal Office of State Cooperation resulted from a formal request of the Association of Food & Drug Officials (AFDO). This new office eventually would become the U.S. Food and Drug Administration (FDA)'s Division of Federal State Relations and today is known as FDA's Office of Partnerships.

Affairs Professional Society and the USDA Food Safety and Inspection Service Annual Federal/State Conference on Food Safety; he explains AFDO's vision of a national Integrated Food Safety Systen (IFSS). He requests support from USDA and FDA to convene a meeting of a group to develop a blueprint for an integrated national food regulatory system.



FSMA - IFSS/PFP 2

1998 The National Food Safety System is formed following a 50-state meeting. Workgroups consisting of federal, state and local government officials begin developing projects to advance the vision of an integrated system.

2009 The PFP (Partnership for Food Protection) is established to help implement the recommendations from the 2008 50-State Workshop. The PFP will be designated the primary group to advance and build the IFSS.

2011 FSMA is passed. It directs FDA to build an IFSS in partnership with state and local authorities.

Domestic capacity





Where to Begin?



- 351 Health agencies spread out among state, county, city, and township.
- Where do we begin to build an integrated system?

We can begin here!

FSMA & Fed-State Integration

- Federal-State Integration Deliverable Groups
 - Operational Partnerships
 - Sections 201, 209, 210
 - Capacity Building
 - Sections 205c1, 205c2
 - Training
 - Section 209
- Harmonize with PFP Workgroups



5



U.S. Food and Drug Administration
Protecting and Promoting Public Health

6

Section 201- Targeting of Inspection Resources for Domestic Facilities

- FDA reliance on inspections conducted by other agencies under agreement
 - States conduct 60% of Federal inspections under contract
- Role of MFRPS and AFRPS
 - Provide uniformity and consistency among Federal & State Inspection Programs
- Independent Audit Group
 - Ensure uniform implementation of Standards
- PFP WGs: National Workplan, National Standards, Oversight

Section 209- Improving the Training of State, Local, Territorial and Tribal Officers

- Set standards and administer training and education programs for food safety officials
- Training areas include:
 - Scientific; best practices; sampling & laboratory; building enforcement actions; inspections under 702/704
- Provide consistency and equivalency among Federal & State Programs
- We must invest in training
 - A contract or MOU will provide support for this effort
- PFP WGs: Training & Certification

U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

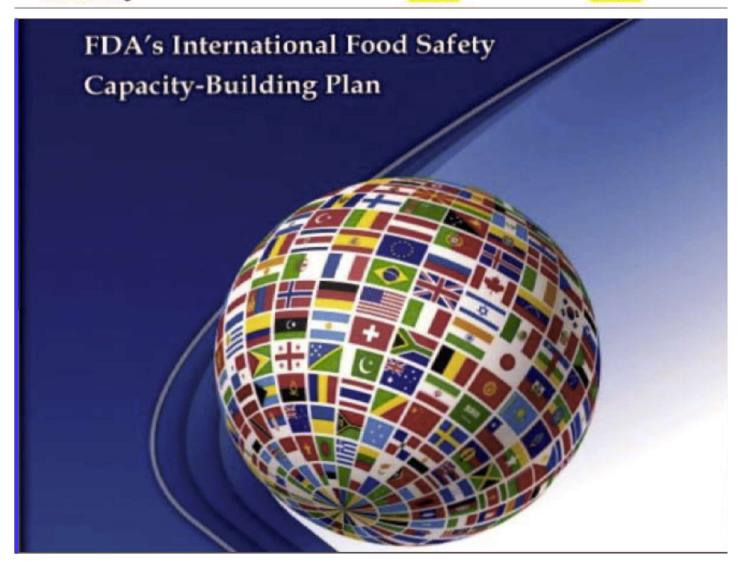
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FSMA & the PFP 50-State Workshop

- 50-State Workshop Breakout Sessions
 - From Ideas to Implementation: Facilitating & supporting the use of IFSS best practices
- Tie in: PFP Training & Certification Workgroup
 - Link sections of FSMA to IFPTI Curriculum Framework
 - Identify and Qualify Existing Job and Occupational Analyses
 - Seven (7) job task analyses have been identified
 - Currently developing criteria to qualify these job task analyses
 - Grants: IFPTI, NEHA, UC Davis, IA State Univ, Auburn Univ, NCSU, Univ of TN

Then & Now: Investment in Federal-State Integration

Programs	FY2009 Funding	FY2012 Funding
Contracts (total)	\$21M	\$24M
Egg Contract (added FY11)	None	\$300K
MFRPS (part of Food Contract)	26 Programs	40 Programs
Grants (total)	\$17.4M	\$48.1M
MFRPS (added FY12)	None	\$11M
ISO (added FY12)	None	\$8M
RRT (expanded FY12)	\$4.5M	\$6M
FSMA Emergency Response & Risk Based Inspections	None	\$4M
Alliances	None	AFDO & NCSL
State Cooperative Programs (total)	\$250K	\$2.45M
Retail	\$250K	\$500K
Dairy & Shellfish	None	\$250K
Total Funding	\$38.7M	\$72.9M



Key Goals & Objectives

Goal 3: Support the exchange of information between FDA and foreign government agencies or other entities

Objective 3.1 Support bilateral and multilateral arrangements and agreements with foreign governments, including provisions to provide for responsibility of exporting countries to ensure food safety (Element 1 of FSMA's Section 305)

Objective 3.2 Establish new or identify existing mechanisms to support secure electronic data sharing with foreign governments or other entities (Element 2 of FSMA's Section 305)

Objective 3.3 Explore appropriateness of relying on mutual recognition of inspection reports (Element 3 of FSMA's Section 305)

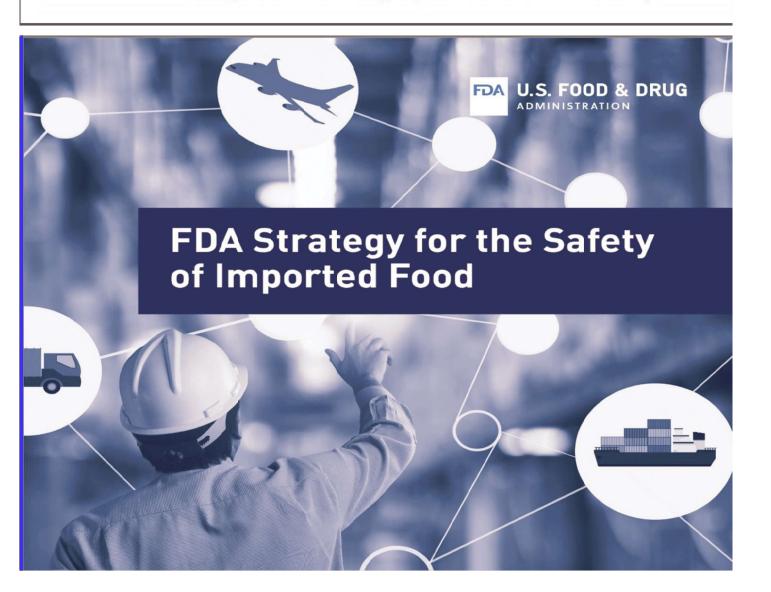
Goal 4: Enhance technical assistance and capacity building in food safety

Objective 4.1 Work with partners to develop/deliver food safety training programs focused on best practices and global food safety principles

Objective 4.2 Train foreign governments and food producers on U.S. requirements for safe food (Element 4 of FSMA's Section 305)

Objective 4.3 Develop recommendations on whether and how to harmonize requirements unde the Codex Alimentarius (Element 5 of FSMA's Section 305)

Objective 4.4 Support provisions for the multilateral acceptance of laboratory methods and testing and detection techniques (Element 6 of FSMA's Section 305)



FDA Strategy to Ensure Imported Food Safety - 1

GOAL 1: Food Offered for Import Meets U.S. Food Safety Requirements

Objective 1.1: Optimize use of foreign inspections

- * Objective 1.2: Ensure importer use of verified foreign suppliers through effective implementation of the Foreign Supplier Verification Programs final rule
- * Objective 1.3: Take into account the public health assurances of reliable audits such as those issued under FDA's Accredited Third-Party Certification Program or pursuant to other assurance programs aligned with FDA food safety requirements
- * Objective 1.4: Incentivize importers to use verified suppliers of safe food through the Voluntary Qualified Importer Program Objective 1.5: Leverage the oversight efforts of regulatory counterparts with strong food safety systems

Objective 1.6: Increase awareness of and training on food safety requirements and strengthen the capacity of foreign suppliers to produce safe food

17

FDA Strategy to Ensure Imported Food Safety - 2

GOAL 2: FDA Border Surveillance Prevents Entry of Unsafe Foods

Objective 2.1: Continue to enhance and refine FDA's import screening and entry review processes

Objective 2.2: Optimize use of physical examination and sampling of imported food

Objective 2.3: Strategically utilize import alerts and import certifications

Objective 2.4: Improve testing methodologies and tools used to determine admissibility of food offered for import

Objective 2.5: Maximize the benefit to border surveillance from state and other partnerships



GOAL 3: Rapid and Effective Response to Unsafe Imported Food

Objective 3.1: Maximize effectiveness of FDA response to an event involving an imported food

Objective 3.2: Enhance the efficiency and effectiveness of imported food safety recalls

Objective 3.3: Use information-sharing opportunities to prepare for and respond to the entry of unsafe imported food

19

FDA Strategy to Ensure Imported Food Safety - 4

GOAL 4: Effective and Efficient Food Import Program

Objective 4.1: Optimize resource allocation by developing a comprehensive global inventory of food facilities and farms and assessing the cumulative oversight applied to the global inventory Objective 4.2: Ensure effectiveness of import activities through performance assessment and continuous improvement

Strategy to Ensure Exports to U.S. Food Safety?

GOAL 1: Understand the U.S. system vision - IFSS
Objective 1.1 work with AmCham F&B Committee and VCCI F&B
Working Group to launch an annual "Food Safety Forum"

GOAL 2: Cooperate with U.S. importers on the FSVP and the VQIP

Objective 2.1 cooperate with importers and third-party certification bodies, such as SGS, to become a "qualified foreign supplier."

GOAL 3: Sign a USDA/FDA/MOH/MARD MOU for food safety cooperation



Cám ơn vì đã lắng nghe ...!

Thank you for listening ...!

21



FSMA AND FOOD QUALITY ASSURANCE ISSUES

Mr. Lam Van Xu – AFL Food Lab Manager – SGS Viet Nam



FSMA & FOOD QUALITY ASSURANCE ISSUES

Lam Van Xu – Food Laboratory, SGS Vietnam

WHEN YOU NEED TO BE SURE





FSMA RULES & THEIR APPLICABILITY

FSMA aims to ensure the U.S. food supply is safe by shifting the focus from **responding** to contamination to **preventing** it, hence strengthen the food safety system

7 Rules of FSMA	Manufacture, Processing, Dist'n Centers & Warehouses - Human Food	Manufacture, Processing, Dist'n Centers & Warehouses - Animal Food	US Importers of Human & Animal Food	Produ ce Farms	US Shippers, Carriers, Receivers of Human & Animal Food
Preventive Controls for Human Food (PCHF)	X				
Preventive Controls for Animal Food (PCAF)		x			
Foreign Supplier Verification Program FSVP			×		
Produce Safety				X	
Sanitary Transportation (US)					X
Intentional Adulteration (Food Defense)	X				
Third Party Accredited Certification rule (voluntary)	х	х		x	

2

Source: FDA



WHICH FSMA RULES APPLY TO YOU?



- Preventive Controls -Human Food (21 CFR Part 117)
- Intentional Adulteration Rule "Food Defense" (21 CFR Part 121)



 Produce Safety Rule (21 CFR 112)



Source: from Hank Karayan presentation

3

COMPLIANCE

REGULATION



21 CFR PART 117 PREVENTIVE CONTROLS - HUMAN FOO

- 21 CFR Part 117 Current GMP, Hazard analysis & Risk Based Preventive Controls for human food
- A. General provisions
- B. Current Good Manufacturing Practice
- C. Hazard analysis and risk-based preventive controls
- D. Modified requirements for certain facilities
- E. Withdrawal of a qualified facility exemption
- Requirements for records that must be established and maintained
- G. Requirements for supply-chain program



21 CFR PART 117 STANDARDS FOR PRODUCE SAFETY



Focus on conditions and practices identified as potential contributing factors for microbial contamination

- Agricultural water
- Biological soil amendments of animal origin
- Worker health and hygiene
- Equipment, tools, buildings and sanitation
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Sprouts requirements

5



DEFINITION: HAZARD

- Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury
 - Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
 - Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
 - Physical hazards (such as stones, glass, and metal fragments)
- The hazard occurs naturally; may be unintentionally introduced; may be intentionally introduced for purposes of economic gain



Food	Microbiological standards	Antibiotic	Additive	Pesticide	NIP & Allergen	Process contaminants	Others
Seafood	Annex 5 - Fish and Fishery Products Hazards and Controls Guidance - Fourth Edition	Annex 5 - Fish and Fishery Products Hazards and Controls Guidance - Fourth Edition	$\begin{array}{c} \underline{\text{Title 21}} \rightarrow \\ \underline{\text{Chapter I}} \rightarrow \\ \underline{\text{Subchapter}} \\ \underline{\text{B}} \rightarrow \underline{\text{Part}} \\ \underline{172} \end{array}$	40 CFR Part 180, Subpart C - Specific Tolerances	Title 21 → Chapter I →	Annex 5 - Fish and Fishery Products Hazards and Controls Guidance - Fourth Edition	
Agri product s	USDA AMS recommendation: TPC <50,000 CFU/g, Yeast <10,000 CFU/g, Mold <10,000 CFU/g, Coliform <100 MPN/g, E. coli <3 MPN/g. FSMA: Salmonella & Listeria monocytogene: Negative	-	$\begin{array}{c} \textbf{Title 21} \rightarrow \\ \textbf{Chapter I} \rightarrow \\ \textbf{Subchapter} \\ \hline \textbf{B} \rightarrow \textbf{Part} \\ \hline \textbf{172} \\ \end{array}$		Title 21 → Chapter I ⇒ Subchapte r B → Part 101.9	-	Official U.S. Standards



- Coliforms
- E. Coli: Shiga toxin
- Listeria monocytogenes
- Salmonella
- Vibrio species
 - Vibrio cholerae
 - Vibrio parahaemolyticus
 - Vibrio vulnificus
- Staphylococcus aureus: Staphylococcal enterotoxin
- Clostridium botulinum: Botulinum type A, B, E and F neurotoxin
- Hepatitis A, Norovirus





Potential Preventive Control

- Process controls that kill pathogens
 - Cooking, heating...
- Process controls that prevent growth
 - Time/temperature controls
 - Moisture control (water activity)
 - Checking formulation (preservatives, high salt content...)
- Supply chain programs for sensitive ingredients used without a kill step
- Sanitation controls that prevent recontamination





CASE STUDEY: BIOLOGICAL HAZARD

Case 1: Vibrio parahaemolyticus

 EU Alert: frozen whole raw shrimps from Vietnam (Jul-18)

· FDA alert: Crab Meat from Venezuela (Jul-18)

 SGS VN: Many samples detected with Vibrio Para

- Contamination source:
 - o Estuaries, Coastal waters: raw or uncooked shrimps were often detected with V. Para
 - o Poor separation among cooked and uncooked seafood production lines

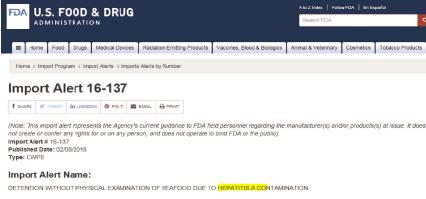




Case 2: Hepatitis A

Seafood and frozen fruit/vegetable

FDA alert: 2016 (scallop, frozen strawberries), 2017 (Tuna)



Contamination Source: Unsafe water, Inadequate sanitation/Poor personal hygiene, workers suffering from symptoms of hepatitis A, unsupervised areas that shellfish is commercially distributed



BIOLOGICAL HAZARD

- Potential Preventive Control
 - Environmental Monitoring
 - If applicable, required to verify the effectiveness of preventive controls for environmental pathogens.

E.g., facilities where ready-to-eat product is exposed to the environment

- · Must be tailored to each facility
- A useful program diligently tries to find the organism and addresses issues identified
- Make sure to have a complete environmental monitoring program in place

SAFEGUARD



CHEMICAL HAZARD

- Veterinary drugs including antibiotics
 - Chloramphenicol, Nitrofurans, Fluoroquinolones, Sulfonamides
- Additive and preservatives
- Pesticides
- Mycotoxins
- Heavy metals
- Toxic residues from process contamination
- Allergens

Potential Preventive Control

- Supply chain programs
- Processing controls to prevent cross contamination or minimize contamination
- Allergen labeling

13



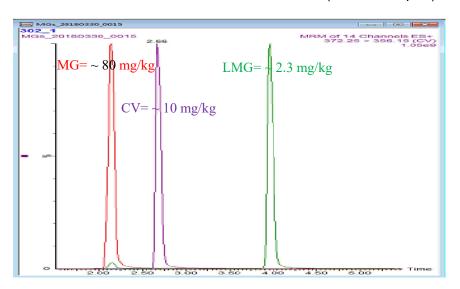
CHEMICAL HAZARD





Case study 1: (Leuco)Malachite green & Crystal violet

Cross-contamination from the blue or black ink (CD marker/pen)



Result of MG, LMG and CV in one of the pens in the market

15



CASE STUDY: CROSS CONTAMINATION

Case study 2: SEM (Nitrofurazone Metabolite)

SEM: semicarbazide; NPSEM: 3[(2-nitrophenyl)methylene]-hydrazinecarboxamide; o-NBA: ortho-nitrobenzaldehyde. Source: Vass et al. (2008).



Case study 2: SEM (Nitrofurazone Metabolite)

Recently, there are many articles to show that SEM is not good marker to indicate the abuse of nitrofurazone (nitrofuran parent drug) with the reasons here.

- It naturally occurs in crustacean, particularly in the shell of shrimp and crab.
- It come from degradation of azodicarbonamide in flour
- It presents in the foods contained in glass jars and bottles closed with metal lid sealed with plastic gaskets (food migration). The example of food products in this case are fruit juice, jam, mustard, and tomato ketchup.
- It also found in the food ingredients such as salt and spice, egg powder, and carrageenan. Nobody can prove how SEM is generated in these products.
- In addition, it may come from the bleaching agents used to improve color and appearance of fish fillets.

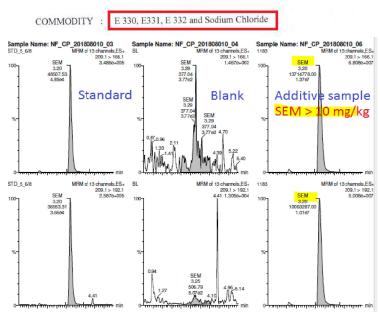
17



CASE STUDY: CROSS CONTAMINATION

Case study 2: SEM (Nitrofurazone Metabolite)

CERTIFICATE OF ANALYSIS



SEM result > 10 mg/kg (additive E330, E331, E332 and salt NaCl)



Case study 2: SEM (Nitrofurazone Metabolite)

- To ensure that the residue of SEM in foods comes from the drug abuse, EU Community Reference Laboratory/USDA recommended a guideline/method to confirm by bound residues
- http://cordis.europa.eu/result/rcn/42345 en.html
- https://www.fsis.usda.gov/wps/wcm/connect/9104c880-cf55-4b30-90b6-8d3f60c22a01/CLG-NFUR3.pdf?MOD=AJPERES





NOTE ON ANALYSIS OF NITROFURANS RESIDUE SEMI-CARBAZIDE CONFIRMATION Sanders P

- 1 When testing composite food, only analyze the part of the product which is of animal origin, for example only the meat part of breaded products.
- 2- The detection of total (free+ bound) residues of metabolites of nitrofurans can be maintained at the screening level.
- 3- In case of a non compliant sample for total SEM, a sample must be reanalyzed for the bound residues of SEM only. To this end, free SEM should be extracted/washed out prior to this confirmation test.

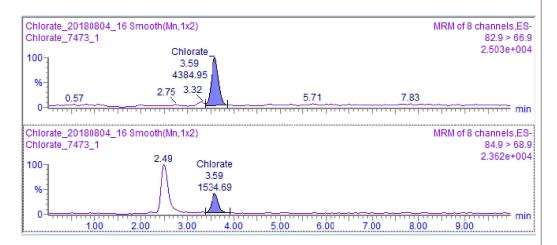
19



CASE STUDY: CROSS CONTAMINATION

Case study 3: Chlorate

Often detected on seafood and fruit/vegetable treated with chlorine



Result of chlorate in a shrimp sample treated with chlorine: 0.11 mg/kg



Case study 4: Pesticide

- Products containing the plant origin ingredients
- Cross contamination during farming or the use of surfactants, disinfectants, biocides...
 - · Trifluralin (a herbicide agent)
 - Ethoxyquin (as antioxidant preservative in feed)
 - BAC (Benzalkonium Chloride) and DDAC (Dialkyldimethylammonium Chloride) (a cationic surfactant, disinfectant,...)
 - · Chlorpyrifos
- Zero tolerance (default LOQ: 0.01 mg/kg)
- Number of pesticides tested by FDA in 2016: ~ 710 compounds using 3 methods (multi-pesticide screening, glyphosate and acid herbicide methods)

TRUST

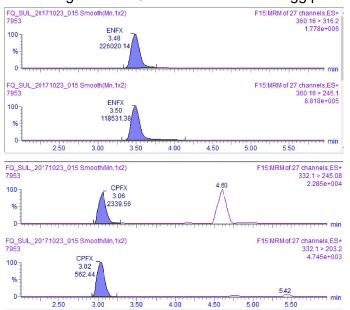
21



CASE STUDY: CONTAMINATION FROM INGREDIENTS

Case study 5: Enrofloxacin & Ciprofloxacin

Source: the ingredients. One of the cases was egg powder.

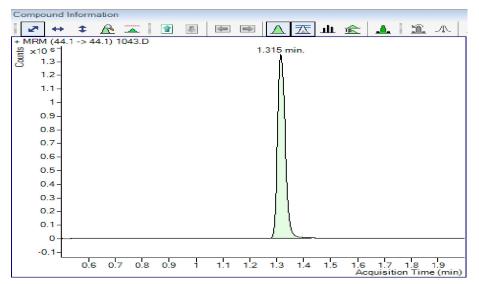


Enrofloxacin (395 μg/kg) and Ciprofloxacin (18μg/kg) in egg powder



Case study 6: Carbonate (E 500-E 501)

 Seafood treated with non-carbonate additive was detected with carbonate!



Result of carbonate (as HCO₃-): 0.076 % (w/w)

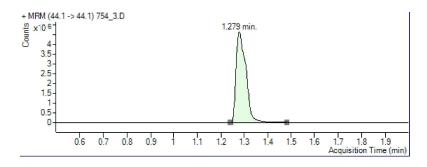
23



CASE STUDY: CONTAMINATION FROM INGREDIENTS

■ Case study 6: Carbonate (E 500-E 501)

Result of carbonate (as HCO₃-) in non-carbonate declared additive:
 Overload of GC-MS detector



Carbonate (as HCO₃-) content (24%) in the additives declared non-carbonate

24



CASE STUDY: PROCESS CONTAMINANTS

- Acrylamide
- Glycidyl fatty acid esters & 3-MCPD fatty acid esters in oil
- Polyaromatic hydrocarbon (PAH)
 - Dried by traditional method using wood or charcoal for combustion.
 Anthraquinone also occurs so it can be used as an indicator.
- Allergen
 - 90% of food allergic reactions are caused by these allergens: Gluten, Milk, Egg, Crustacean, Fish, Peanut, Soya, Tree nuts ("Big 8")







POTENTIAL PREVENTIVE CONTROL

- Supply chain programs for sensitive ingredients to control contamination through verification by onsite audit, document review, testing...
- Process controls to prevent growth or kill pathogens; to prevent cross contamination or minimize contamination
- Environmental Monitoring
- Transparency declaration for allergens







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2

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FSPCA PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL (PCQI) TRAINING

THỜI LƯỢNG: 3 NGÀY

NGÀY ĐÀO TẠO: 24, 25, 26/04/2019

ĐỊA ĐIỂM: TRUNG TÂM ĐÀO TẠO SGS, LẦU 3, 115 VÕ VĂN TẦN, P6, Q3, TP. HCM

NGÔN NGỮ ĐÀO TẠO: TIẾNG VIỆT

CHI PHÍ: 14,000,000 VND/ NGƯỜI (10% DISCOUNT CHO 2 HỌC VIÊN TRỞ LÊN)

CHỨNG CHỈ: OFFICIAL FSPCA PCQI CERTIFICATE BY THE ASSOCIATION OF FOOD AND

DRUG OFFICIALS (AFDO)

ĐĂNG KÝ

(+84) 8 3935 1920 ext: 244 or 094.481.2266 (Ms Van)

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MÔ TÁ KHÓA HỌC

Khóa học này được phát triển bởi FSPCA, nó là một "Chương trình chuẩn" được tổ chức bởi FDA.

Mục tiêu chính của khóa học này là cung cấp kiến thức cho nhóm an toàn thực phẩm của các doanh nghiệp sản xuất thực phẩm để họ trở thành PCQI (cá nhân đạt tiêu chuẩn cho việc thiết lập, thẩm định, theo đối, thẩm tra và thiết lập lại một hoặc nhiều kế hoạch an toàn thực phẩm theo luật về kiểm soát phòng ngừa trong thực phẩm). Theo như Bộ Luật Hiện đại hóa an toàn vệ sinh thực phẩm (FSMA) của FDA Hoa Kỳ, các cơ sở được yêu cầu phải tuân thủ theo quy định này, thì phải có nhân viên PCQI để phát triển kế hoạch an toàn thực phẩm theo yêu cầu kiểm soát phòng ngừa. Khóa học này cung cấp thông tin liên quan đến các quy định và yêu cầu có liên quan mà các nhà máy thực phẩm phải thực hiện cho kế hoạch an toàn thực phẩm của họ. Các quy định yêu cầu một số hoạt động nhất định phải được hoàn thành bởi "một cá nhân được công nhận về kiểm soát phòng ngừa" – người phải "hoàn thành khóa đào tạo phát triển và ứng dụng kiểm soát phòng ngừa dựa trên rủi ro". Khóa học này được FSPCA phát triển - là "giáo trình chuẩn hóa" được công nhận bởi FDA; và việc hoàn thành khóa học này là một cách để đáp ứng các yêu cầu cho một "cá nhân được phê duyệt về kiểm soát phòng ngừa".

ĐÓI TƯỢNG HỌC VIÊN

Đại diện các nhà máy thực phẩm có xuất khẩu sản phẩm của mình sang Mỹ

Những thành phần khác quan tâm đến quy định mới của FDA Hoa Kỳ và kiểm soát phòng ngừa Theo Quy định về kiểm soát phòng ngừa thực phẩm cho con người, Những "Cá nhân được công nhận về việc kiểm soát phòng ngừa" có thể thực hiện những việc dưới đây:

- Chuẩn bị một kế hoạch An toàn thực phẩm
- Thẩm định các biện pháp kiểm soát phòng ngừa
- Xem xét báo cáo
- Cập nhật việc phân tích mối nguy của kế hoạch An toàn thực phẩm

NỘI DUNG ĐÀO TẠO

Ngày thứ nhất:

- Phần 1: Giới thiệu lớp học
- Phần 2: Tổng quan kế hoạch an toàn thực phẩm
- Giải lao
- Phần 3: GMPs và các chương trình tiên quyết khác
- Phần 4: Các mối nguy an toàn thực phẩm - sinh học
- Nghỉ trưa
- Phần 5: Các mối nguy an toàn thực phẩm hóa học, vậy lý và kinh tế
- Giải lao
- Phần 6: Các bước sơ bộ phát triển một kế hoạch an toàn thực phẩm
- Phần 7: Nguồn lực cho kế hoạch an toàn thực phẩm

Ngày thứ hai

- Ôn lại nội dung của ngày đầu và thảo luân
- Phần 8: Phân tích mối nguy và xác định biện pháp kiểm soát phòng ngừa
- Giải lao
- Phần 9: Quy trình kiểm soát phòng ngừa
- Nghỉ trưa
- Phần 10: Kiểm soát phòng ngừa chất gây dị ứng
- Phần 11: Chương trình vệ sinh phòng ngừa
- Phần 12: Chương trình kiểm soát phòng ngừa về chuỗi cung ứng

Ngày thứ ba (Nửa ngày)

- Ôn lại nội dung của ngày thứ hai và thảo luân
- Phần 13: Thủ tục Thẩm tra và thẩm định
- Phần 14: Thủ tục kiểm soát tài liêu - hồ sơ
- Giải lao
- Phần 15: Kế hoach Thu hồi
- Phần 16: Tổng quát về các qui định – cGMP, Phân tích mối nguy, và Biện pháp kiểm soát dựa trên cơ sở mối nguy dành cho Thực phẩm cho người
- Tổng kết Bài kiểm tra



SGS ACADEMY

TRANSFORMING PEOPLE AND BUSINESSES

TÀI LIỆU VÀ CHỨNG CHỈ

Tài liệu chương trình chuẩn đáp ứng yêu cầu của FDA. Tài liệu đào tạo FSPCA này được thiết kế phù hợp với việc đào tạo theo Điều 21 Nguyên tắc Liên bang phần 117.180(c)(1) dành cho cá nhân được công nhận về việc kiểm soát phòng ngừa, những người được quyền thực hiện một kế hoạch An toàn thực phẩm



Giảng viên là chuyên gia được phê duyệt về năng lực và kinh nghiệm và đã thành công hoàn tất khóa tập huấn trở thành giảng viên chính bởi FSPCA.

Học viên của khóa học này sẽ nhận được Giấy Chứng Nhận chính thức được cấp bởi IFPTI (International Food Protection Training Institute)



dưới sự chấp thuận của Association of Food and Drug Officials (AFDO) và and IFSH (Institute for Food Safety and Health) – Cơ quan quản lý các khóa đào tạo PCQI khi thành công hoàn thành khóa đào tao.







LỊCH ĐÀO TẠO SGS NĂM 2019 – TP. HỒ CHÍ MINH



SGS TRAINING CALENDAR 2019 - HOCHIMINH CITY

CODE	COURSE TITLE	DURATION (DAYS)	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ОСТ	NOV	DEC	
			LAC	- Lead A	Auditor '	Trainin	g Course	es							
	CÁC KHÓA ĐÀO TẠO CHUYÊN GIA ĐÁNH GIÁ TRƯỞNG														
LAC-01	Chuyên gia Đánh giá Trưởng ISO 9001 ISO 9001 – IRCA Lead Auditor	05	21 - 25			8 - 12				5 - 9			11 - 15		
LAC-02	Chuyên gia Đánh giá Trưởng ISO 14001 ISO 14001 – IRCA Lead Auditor	05				22 - 26					23 - 27				
LAC-03	Chuyên gia Đánh giá Trưởng FSSC 22000 FSSC 22000 – IRCA Lead Auditor	05					20 - 24					07 - 11			
LAC-04	Chuyên gia Đánh giá Trưởng ISO 45001 ISO 45001 – IRCA Lead Auditor	05						17 - 21						16 - 20	



27 - 29

01 - 03

04 - 06

45001:2018

HSM-

01-01

ISO 45001:2018 Awareness & Internal

Nhận thức & Đánh giá nội bộ ISO

03



CODE	COURSE TITLE	DURATION (DAYS)	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ОСТ	NOV	DEC	
	IMS –Integrated Management Training courses ĐÀO TẠO HTQL TÍCH HỢP CHẤT LƯỢNG – MÔI TRƯỜNG – AN TOÀN – XÃ HỘI														
IMS -02	ISO 9001 - ISO 14001 Integration Internal Auditor Đào tạo Đánh giá Nội bộ tích hợp ISO 9001 - ISO 14001	03		06 - 08				10 - 12				14 - 16			
IMS-04	ISO 9001 - OHSAS 18001 Integration Internal Auditor Đào tạo Đánh giá nội bộ HTQL tích hợp ISO 9001 – OHSAS 18001	03				03 - 05				12 - 14				04 - 06	
IMS-06	ISO 9001 - 14001 - OHSAS 18001 Integration Internal Auditor Đánh giá Nội bộ HTQL tích hợp ISO 9001 – ISO 14001 – OHSAS 18001	04						11 - 14						03 - 06	
IMS -10	ISO 9001 & SA8000 Internal Auditor Đào tạo Đánh giá Nội bộ HTQL tích hợp ISO 9001 – SA 8000	03			11 - 13						04 - 06				
	SAS – Social Standards ĐÀO TẠO TCHTQL TRÁCH NHIỆM XÃ HỘI														
SAS-05	Social Compliance Auditor Đánh giá viên Hệ thống Trách nhiệm xã hội	03			25 - 27				08 - 10				18 - 20		



CODE	COURSE TITLE	DURATION (DAYS)	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ОСТ	NOV	DEC	
	Training of Other International Standards ĐÀO TẠO CÁC TIÊU CHUẨN QUỐC TẾ KHÁC														
EnMS- 05	ISO 50001:2011 Awareness and Internal Auditor Training Nhận thức và Đánh giá nội bộ ISO 50001:2011	03		11 - 13				17 - 19							
RMS-03	ISO 31000 Risk Management Awareness and Internal Auditor Training Đào tạo Nhận thức và Đánh giá nội bộ ISO 31000 - Quản lý rủi ro	03				15 - 17						21 - 23			
ITS-03	ISO/IEC 27001:2005 Awareness and Internal Auditor Training Đào tạo Nhận thức và Đánh giá nội bộ ISO/IEC 27001:2013	03						12 - 14						11 - 13	
ITS-01	ISO/IEC 27001:2013 Awareness Training Đào tạo Nhận thức về hệ thống quản lý An ninh thông tin theo tiêu chuẩn ISO/IEC 27001:2005	02	10 - 11												
MDS-01	Awareness training of ISO 13485 Đào tạo nhận thức ISO 13485	02			18 - 19				03 - 05						
MDS-03	Awareness and Internal Auditor of ISO 13485 Đào tạo Nhận thức và đánh giá nội bộ ISO 13485	03					06-08				18 - 20				
FSC-01	FSC CoC Training Đào tạo tiêu chuẩn FSC CoC	01				01					13				



CODE	COURSE TITLE	DURATION (DAYS)	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ост	NOV	DEC	
					try Stan										
	ĐÀO TẠO CÁC TIÊU CHUẨN NGÀNH Ô TÔ														
TSM-01	IATF 16949:2016 Awareness and Internal Auditor Training Nhận thức và Đánh giá viên nội bộ IATF 16949:2016	03			25 - 27						16 -18				
TSM-02	IATF 16949:2016 Five core Tools 5 công cụ IATF 16949:2016	04				01 - 04						21 - 24			
TSM-03	VDA - Quality Management in the Automotive Industry - Process Audit Part 3 - Awareness Training Nhận thức VDA - QLCL cho ngành ô tô - đánh giá quá trình Phần 3	02		25 - 26						19 - 20					
TSM-04	VDA - Quality Management in the Automotive Industry - Process Audit Part 3 - Internal Audit Training Đào tạo đánh giá nội bộ VDA - QLCL cho ngành ô tô - đánh giá quá trình Phần 3	03				17 - 19						30- 31/10; 01/11			



CODE	COURSE TITLE	DURATION (DAYS)	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ОСТ	NOV	DEC
		Ð	Foo ÀO TẠC	d Indus) DÀNH	try Trai CHO NG	ning Co ÀNH TH	urses ỰC PHÁ	ĹМ						
FSH-05	ISO/FSSC 22000 Awareness and Internal Auditor Training Nhận thức và Đào tạo đánh giá nội bộ ISO/FSSC 22000	03	16 - 18				08 - 10		15 - 17			16 - 18		
FSH -18	BRC V8 Food Safety Awareness and Internal Auditor Training Nhận thức và đánh giá viên nội bộ BRC V8	03			13 - 15		15 - 17		22 - 24				25 - 27	
FSH -24	HACCP Awareness and Internal Auditor Training Nhận thức và đánh giá viên nội bộ HACCP	03			18 - 20						09 - 11			
FSH - 34	FSMA Preventive Controls Qualified Individual Kiểm soát phòng ngừa thực phẩm cho người theo FSMA	03				24 - 26			24 - 26			14 - 16		23 - 25



CODE	COURSE TITLE	DURATION (DAYS)	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ОСТ	NOV	DEC	
	Management & Improvement Tools Training Courses ĐÀO TẠO CÔNG CỤ QUẢN LÝ VÀ CẢI TIẾN														
7QC-01	Seven Quality Control Tools 7 công cụ Quản lý chất lượng	02						06 - 07						05 - 06	
MST-01	Root cause analysis and Problem solving Truy tìm nguyên nhân gốc và Giải quyết vấn đề	02			11 - 12					26 - 27					
MST-02	Supplier Auditing Skills Training Kỹ năng Đánh giá nhà cung cấp	02					09 - 10						07 - 08		
	Leadership & Personal Development Training Courses ĐÀO TẠO KỸ NĂNG LÃNH ĐẠO & PHÁT TRIỂN CÁ NHÂN														
MSP-04	Customer Service Training Đào tạo về Dịch vụ khách hàng	02			18 - 19			20 - 21			12 - 13				
MSP-05	Communication Skills Training Kỹ năng Giao tiếp hiệu quả	02	24 - 25			22 - 23				12 - 13			28 - 29		
MSP-06	Effective Presentation Skills Training Kỹ năng thuyết trình hiệu quả	02		07 - 08				24 - 25			19 - 20				
MSP-06 MSP-12		02 02	10 - 11	07 - 08		01 - 02		24 - 25	11 - 12		19 - 20	24 - 25			



CODE	COURSE TITLE	DURATION (DAYS)	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ОСТ	NOV	DEC
MSP-19	Train the Trainer Kỹ năng giảng dạy cho Giảng viên	03			25 - 26					28 - 30			06 - 08	
LD-00	True Leaders – Mini Version Training Đào tạo kỹ năng lãnh đạo - Phiên bản Mini	02		31/01 & 01/02		01 - 02			18 - 19	19 - 20	03 - 04	30/09 & 01/10	01 - 02	26 - 27
LD-00	True Leaders – Full Version Training Đào tạo kỹ năng lãnh đạo - Phiên bản gốc	02		11 - 12		08 - 09		03 - 04		15 - 16		28 - 29		
LD-01	Emerging Leadership Training Đào tạo Khởi sự làm lãnh đạo	02		25 - 26		15 - 16		20 - 21		26 - 28		21 - 23		11 - 13
LD-04	Supervision and People Management - Midway Leadership Training Đào tạo Giám sát và Quản lý con người – Giữa chặng đường lãnh đạo	02	03-04		07 - 08		06 - 07		08 - 10		23 - 25		18 - 19	
LD-07	Leadership for Senior Managers Training Khóa học Lãnh đạo cấp cao	02	28 -29				23 - 24					14 - 15		
LD-02	Leaders never mind difficult conversation Training Lãnh đạo không ngại đối thoại	01				19				01		04		
LD-03	Time Management for Managers Training Quản lý thời gian của Lãnh đạo	01			01				05					18
LD-05	Coaching in the work place Training Kỹ năng huấn luyện cho lãnh đạo	01		01			24				05			02
LD-06	Managers lead the teams Training Lãnh đạo đội ngũ	01			04			03			06			02
LD-08	Managing people performance Training Lãnh đạo tạo hướng tới kết quả	01	07			19				09			15	



СО	DE	COURSE TITLE	DURATION (DAYS)	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	ост	NOV	DEC
LD-	-09	Delegation and Task Management - not Productivity only Training Giao việc và Quản lý Công việc - không chỉ là Năng suất	01				05		28			09			09

For more information, please contact:

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