

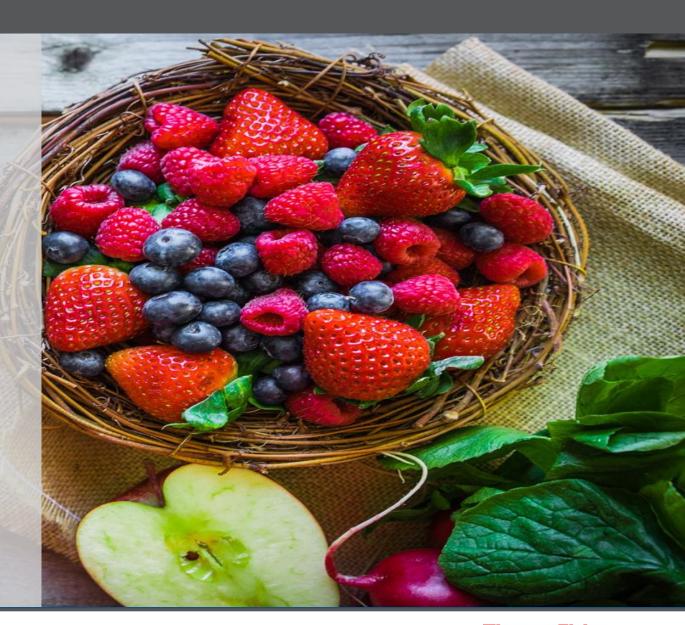
Thermo Fisher SCIENTIFIC

# 2017 Global Food Safety Trends and Regulatory Updates

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### Agenda

- Hot Topics in Food Testing
- FS Testing Market & Trends
- Regulations
- Global Collaborations
- AOAC Projects



### Hot Topics in Food Testing

- Heavy Metals/Metal Speciation- As, Cr, Cd, Hg in rice, apple juice and dietary supplements
- Country of Origin(COO)
- Geographical origin
- Allergen Testing
- Halal foods
- Infant Formula- contaminations and no consumer confidence (melamine, perchlorate issues)
- Functional Foods and Beverages- vitamin waters, energy drinks
- Traditional Chinese Medicine and Ayurvedic Medicine
- Testing for active pharmaceutical ingredients in dietary supplements
- Super fruits ingredients- pomegranate, acai berries
- Natural Substitute Sweeteners- stevia and luo han guo (monk fruit)

### Food Safety Headlines in Asia

### Massive adulterated food scandal unearthed in China

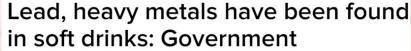
Ingredients for the fake food seasonings include tap water and industrial-grade from human consumption because it can contain cancer-causing agent

By: PTI | Beijing | Published: January 17, 2017 12:53 pm



Fake Branded Sauces and Flavorings using recycled spices and industrial-grade salt which is harmful to human health





PTI | Updated: Nov 22, 2016, 08.16 PM IST

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#### HIGHLIGHTS

- Lead, heavy metals have been found in soft drinks
- Samples of five different cold drinks — Sprite, Mountain Dew, 7UP, Pepsi and Coca Cola — were submitted to National Test House for testing.

## FDA seizes 890kg mangoes artificially ripened with calcium carbide in Ulhasnagar

Pradeep Guptal TNN | Apr 21, 2017, 11.21 PM IST

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BEST OF EXI



ULHASNAGAR: Officials of the Food and Drug Administration (FDA) in a joint operation with staff of Ulhasnagar & Municipal Corporation on Friday raided five godown at the Ulhasnagar. Out of them, from two they seized 890 kg mangoes that were being artificially ripened & with calcium carbide &. The raid was carried out after FDA & officials received specific Information about five



### Global Food Safety Testing Market Size

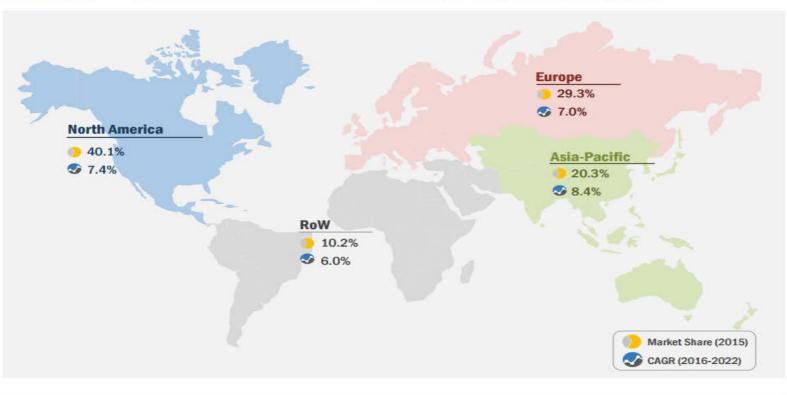


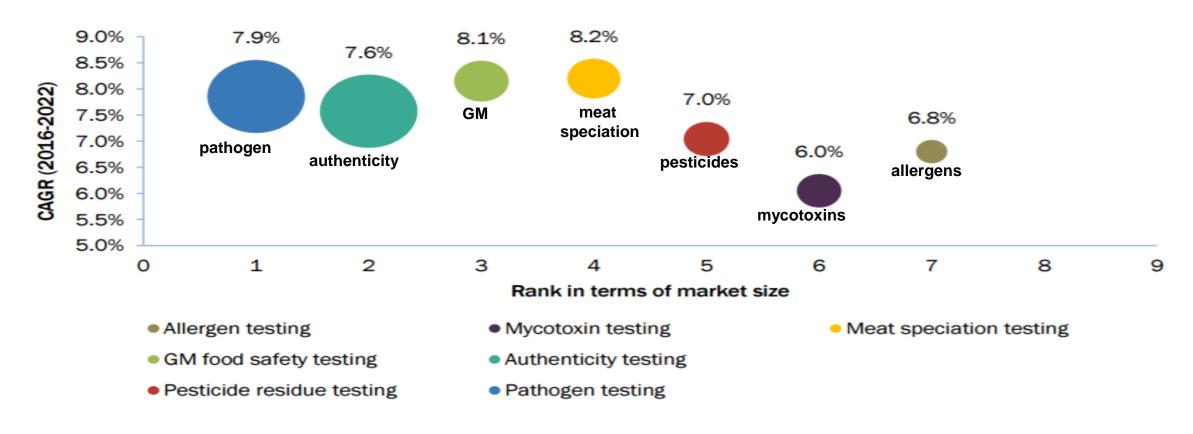
FIGURE 15 FOOD SAFETY TESTING MARKET SHARE (VALUE), BY REGION, 2015

Source: Secondary Research, Primary Interviews, Related Research Publications, Industry Journals, Press Releases, and MarketsandMarkets Analysis

- Global food safety testing market is projected to grow from USD 4.5 Billion in 2015 to USD 18.4 Billion by 2022
- All regions have a good growth rate, highest growth will come from Asia

### Global Food Safety Testing- Projected Market Size 2022

#### FIGURE 8 FOOD SAFETY TESTING MARKET SNAPSHOT, BY SUB MARKETS



Note: Bubble size indicates the projected market size (USD million) by 2022.

Source: Press Releases, Expert Interviews, and MarketsandMarkets Analysis



### Food Safety Testing – Authenticity & GMO's

Authenticity	Genetically Modified Organisms
Market: USD 7.5B by 2022	Market: USD 2.3B by 2022
Growth Region: APAC	Growth Region: NA
<ul> <li>Reason for growth:</li> <li>More fraud detection</li> <li>Labeling fraud</li> <li>Stringent regulations</li> <li>Most adulterated products: fish/seafood, dairy, fruit juices, oils/fats, grains, honey, spices, wine/alcohol, and infant formula</li> </ul>	<ul> <li>Reason for growth:</li> <li>Nutrient consumption</li> <li>Labeling mandates</li> <li>Banned or limited in some countries</li> </ul>

### Food Safety Testing – Meat Speciation & Pesticides

Meat Speciation	Pesticides
Market: USD 2.2B by 2022	Market: USD 1.6B by 2022
Growth Region: APAC	Growth Region: APAC
<ul> <li>Reason for growth:</li> <li>Growing number of economic adulteration cases</li> <li>Stringent food labeling regulations</li> <li>Religious beliefs (halal, kosher, etc)</li> </ul>	<ul> <li>Reason for growth:</li> <li>Testing technology advancement</li> <li>Organic food preference</li> <li>Stringent regulations</li> </ul>

Source: Markets and Markets

### Food Safety Testing – Mycotoxins and Allergens

Mycotoxins	Allergens
Market: USD 1.6B by 2022	Market: USD 760M by 2022
Growth Region: APAC	Growth Region: EU
<ul><li>Reason for growth:</li><li>Humid conditions</li><li>Regulations</li><li>Food recalls</li></ul>	<ul> <li>Reason for growth:</li> <li>Labeling compliance-undeclared allergens biggest issue</li> <li>Growing allergic reactions in consumers</li> <li>Food recalls</li> <li>Stringent regulations</li> </ul>

Source: Markets and Markets

### Food Safety Testing – Bottled Water and Drinking Water

Bottled water	Drinking water
Market: USD 6.8B by 2022	Market: USD 4.1B by 2022
Growth Region: APAC & NA	Growth Region: EU
<ul> <li>Reason for growth:</li> <li>Need for clean and safe water in developing countries</li> <li>Increased bottled water consumption and our on the go lifestyle</li> <li>Convenience</li> </ul>	<ul> <li>Reason for growth:</li> <li>Increase government/private funding for environmental issues</li> <li>Increased pollution and contamination</li> <li>Regulations</li> <li>Check on : chlorine, microorganisms, volatile organic compounds, pesticides, disinfection by products, etc.</li> </ul>

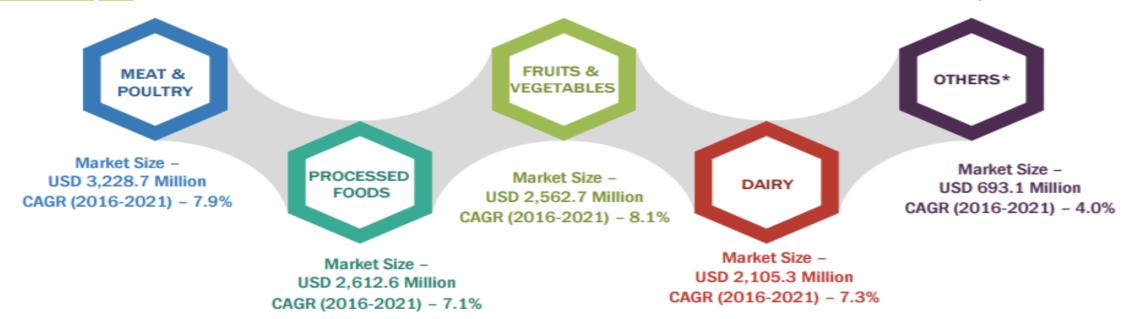
Source: Markets and Markets

### Global Food Safety Testing Market Drivers

- Worldwide increase in the outbreak of foodborne illness
- Stringent regulations
- Accreditation and certification for the testing services by leading labs
- Rapid technological changes
- Globalization in food trade
- Growing food consumption
- Changing lifestyles of consumers
- Demand for convenience food (processed food)

### What Products are Being Tested

#### FIGURE 25 MEAT & POULTRY DOMINATED THE FOOD SAFETY TESTING MARKET, 2015



e- Estimated, p- projected

Source: FAO, WHO, CDC, Food Safety Counsel, EUROLAB, Related Research Publications, Government Publications, Company Press Releases, Company Annual Reports, Company Websites, Company Publications, and MarketsandMarkets Analysis

<sup>\*</sup>Others include cereals and grains.

### Food Safety Challenges

- Developing countries lack controlled infrastructure and resources for food industry
- Manufacturers not aware of food safety regulations
- All countries need to meet international food safety standards
- Time consuming testing methods
- Sample collection issues
- Lack of harmonized food safety regulations

### Global Regulations Update



### Global Food Safety Concerns

- Contamination:
  - Pathogens
  - Chemical
    - Chemical toxins (melamine, pesticide residues)
    - Natural food hazards (non-food fungus, seeds, mushrooms, allergens)
    - Detergents and sanitizers
    - Toxins
    - Antibiotics and steroids (in meat products)
    - Banned Additives
- Economic Adulteration (banned substances being added)
- Mislabeling

### Food Safety – Global Regulatory/Standards Bodies

WHO and FAO

Canadian Institute of Health

AOAC

Food and Drug Administration (FDA),

US Department of Agriculture (USDA)

Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail

**European Food Safety Authority** 

Federal Ministry of Food, Agriculture and Consumer Protection

Food Standard Agency

State Food and Drug Administration

Food Safety and Standards Authority of India

Food and Drug Administration (Latin America)

Food Standards Australia New Zealand



### USA Regulation #1: FSMA

- Food Safety Modernization Act (FSMA) passed in 2011
  - Developed by FDA in response to frequent food product recalls and food-borne illnesses
  - More frequent facility inspections
  - Can suspend registration of a facility
  - Issue mandatory recalls
  - Audit manufacturing facilities
  - FDA can detain any food produced in unsanitary and unsafe conditions
  - Detain food believed to be adulterated or misbranded for 30 days
  - Anyone importing food to the US to inform FDA if any country has refused the entry of the same product
  - For more information: <a href="http://www.fda.gov/Food/FoodSafety/FSMA/default.htm">http://www.fda.gov/Food/FoodSafety/FSMA/default.htm</a>

### USA Regulation #2: cGMP for Dietary Supplements

- As of 2010 all DS companies need to adhere to cGMP guidelines set by the FDA
  - Product needs to be tested (internal or external lab) for quality and safety
  - Test methods must be scientifically valid
  - Standard reference material must be used in the quality test method
  - A detailed record of the test must be maintained

### USA Regulation #3: Proposed Action Level for Arsenic

### Apple Juice

FDA proposed an "action level" of 10 parts per billion (ppb) for inorganic arsenic in apple juice.
 This is the same level set by the Environmental Protection Agency (EPA) for arsenic in drinking water.

#### Bottled Water

The maximum level of arsenic allowed in bottled water is 10 parts per billion (ppb).

#### Rice

• In 2016, the FDA proposed an action level, or limit, of 100 parts per billion (ppb) for inorganic arsenic in infant rice cereal.

### USA Regulation #4: Nutrition Facts Label Change

- Refreshed design
- Updated information about nutrition science
  - Added sugars
  - Actual amounts declared
- Updated serving sizes and labeling requirements for certain package sizes

	OLD		
Nutrit Serving Size 2/3 Servings Per Co	cup (55g)		cts
Amount Per Servin	ng		
Calories 230	Ca	lories fron	n Fat 72
		% Dail	y Value*
Total Fat 8g			12%
Saturated Fat	1g		5%
Trans Fat 0g			
Cholesterol 0	mg		0%
Sodium 160mg			<b>7</b> %
Total Carbohy		7g	12%
Dietary Fiber	4g		16%
Sugars 1g			
Protein 3g			
Vitamin A			10%
Vitamin C			8%
Calcium			20%
Iron			45%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.			
Total Fat Sat Fat Cholesterol Sodium	Calories: Less than Less than Less than Less than	2,000 65g 20g 300mg 2,400mg	2,500 80g 25g 300mg 2,400mg
Total Carbohydrate Dietary Fiber		300g 25g	375g 30g

INCAA	
<b>Nutrition Fa</b>	cts
8 servings per container	<i>(</i> )
Serving size 2/3 cup	(55g)
Amount per serving	
Calories 2	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol Omg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
* The % Daily Value (DV) tells you how much a nutrient in	

a serving of food contributes to a daily diet. 2,000 calories

a day is used for general nutrition advice.

NEW

### USA Regulation #5: USP Ch. 2232 Trace Elements in Dietary Supplements

- Objective of USP Chapter <2232>
  - To limit amounts of elemental contaminants in dietary supplement
  - General chapter not intended to set limits for dietary ingredients
    - Limits set in the corresponding individual monographs.
- Chapter <2232> focuses on four major elements:
  - Arsenic
  - Cadmium
  - Lead
  - Mercury

### LIMITS OF ELEMENTAL CONTAMINANTS

Element	PDE (μg/day) <sup>a</sup>
Arsenic (inorganic)	15
Cadmium	5
Lead	10
Mercury (total)	15
Methylmercury (as Hg)	2

<sup>a</sup> Permitted Daily Exposure (PDE) is derived from the Provisional Tolerable Weekly Intake (PTWI) that is recommended by the Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO) by subtracting the daily exposure (μg/day) to each elemental contaminant from air, food, and drinking water. A body weight of 50 kg and a safety factor are used to calculate the PDE.

Source: USP

http://www.usp.org/sites/default/files/usp\_pdf/EN/USPNF/key-issues/2232\_elemental\_contaminants\_in\_dietary\_supplements.pdf

### USA Regulation #6: Perchlorate

- Naturally occurring mineral found in nitrate fertilizers
- Manmade chemical used as an ingredient for
  - Rocket propellant
  - Explosives
  - Rubber manufacturing
- Perchlorate in irrigation water can build up in crops
- Health risks
  - Interferes with the iodide uptake into the thyroid gland
  - Can disrupt neurological development in children/fetuses
- Found in:
  - Infant Formula
  - Vegetables- lettuce, spinach, tomato, mushrooms
  - Fruits- oranges, grapes, apples, plums and cantaloupes
  - Wine
  - Water



### USA Regulation #6: States Where Perchlorate was Detected in Foods



Ref US FDA 2004-2005 Exploratory Survey Data on Perchlorate in Food

- EPA regulates perchlorate in drinking water since 2011
- EPA acknowledged perchlorate contamination is more widespread in foods then water in US
- FDA I has not yet regulated perchlorate levels in foods. But as of May 4, 2017 the FDA is revoking the
  use of Perchlorate in sealing gaskets for food containers because its use has been abandoned by
  industry.

### **EU Regulatory Updates**

### Food Label Changes

- Clear presentation of allergens (e.g. soy, nuts, gluten, lactose) for prepacked foods
- Mandatory origin information for fresh meat from pigs, sheep, goats and poultry
- List of engineered nanomaterials in the ingredients
- Mandatory indication of the country of origin or provenance for milk, dairy products and meats
- Additional labeling of drinks with high caffeine content with the actual caffeine content listed
  - Example: not recommended for children or pregnant and breastfeeding women

### Inorganic Arsenic

- Food manufacturers must comply with legislation on the amount of toxic inorganic arsenic in their products, warns The Food Standards Agency (FSA)
- European Commission has established maximum limits for iAs in rice and rice products
  - White Rice= 0.20 mg per kg, Brown Rice= 0.25mg/kg. Rice products for children = 0.10 mg/kg

### Thermo Scientific Collaborations



### Collaborations with Regulatory Agencies – Asia

- Analysis of additives in dairy products by liquid chromatography coupled to quadrupole-orbitrap mass spectrometry (Institute of Food Safety, Chinese Academy of Inspection and Quarantine, Beijing)
- Multi-mycotoxin analysis in dairy products by liquid chromatography coupled to quadrupole orbitrap mass spectrometry (Institute of Food Safety, Chinese Academy of Inspection and Quarantine, Beijing)
- Simultaneous determination of dyes in wines by HPLC coupled to quadrupole orbitrap mass spectrometry (Institute of Food Safety, Chinese Academy of Inspection and Quarantine, Beijing)
- High-throughput screening of pesticide and veterinary drug residues in baby food by liquid chromatography coupled to quadrupole Orbitrap mass spectrometry (Institute of Food Safety, Chinese Academy of Inspection and Quarantine, Beijing)

### Collaborations with Regulatory Agencies – Americas

- Multi-mycotoxin Analysis of Finished Grain and Nut Products Using Ultrahigh-Performance Liquid Chromatography and Positive Electrospray Ionization - Quadrupole Orbital Ion Trap High-Resolution Mass Spectrometry (USFDA)
- Development and Validation of a Multiclass Method for Analysis of Veterinary Drug Residues in Milk Using Ultrahigh Performance Liquid Chromatography Electrospray Ionization Quadrupole Orbitrap Mass Spectrometry (Canadian Food Inspection Agency)
- Screening for multiple classes of marine biotoxins by liquid chromatography-high-resolution mass spectrometry (Research Council of Canada)
- Application of Ultrahigh-Performance Liquid Chromatography and Electrospray Ionization
   Quadrupole Orbitrap High-Resolution Mass Spectrometry for Determination of 166 Pesticides in
   Fruits and Vegetables (Canadian Food Inspection Agency)

### Collaborations with Regulatory Agencies – Americas

- Ultrahigh-Performance Liquid Chromatography Electrospray Ionization Q-Orbitrap Mass Spectrometry for the Analysis of 451 Pesticide Residues in Fruits and Vegetables: Method Development and Validation (Canadian Food Inspection Agency)
- Effect of Sample Dilution on Matrix Effects in Pesticide Analysis of Several Matrices by Liquid Chromatography—High Resolution Mass Spectrometry (Ontario Ministry of the Environment)
- Development and Validation of a Qualitative Method for Target Screening of 448 Pesticide
  Residues in Fruits and Vegetables Using UHPLC/ESI Q-Orbitrap Based on Data-Independent
  Acquisition and Compound Database (Canadian Food Inspection Agency)

### Association Of Analytical Communities (AOAC)

#### AOAC INTERNATIONAL

- Globally recognized, independent, third party, not-for-profit association
- Voluntary consensus <u>standards developing</u> organization
- When analytical needs arise- forum to find science-based solutions through the development of microbiological and chemical standards.
- AOAC standards are used globally and they develop fit-for-purpose methods for ensuring quality measurements.
- Website:

https://www.aoac.org/AOAC\_Prod\_Imis/AOAC\_Member/Default.aspx?WebsiteKey=2e25ab5a-1f6d-4d78-a498-19b9763d11b4&hkey=8fc2171a-6051-4e64-a928-5c47dfa25797

- Official Methods of Analysis database/book
- Currently 5 Stake Holder Panels





### **AOAC Projects**

#### Stakeholder Panel for Strategic Food Analytical Methods(SPSFAM)

- Proanthocyanidins in Cranberries (PAC)
- Cannabis Quantitation and Cannabis in Food Products
- BPA in Beverages and Water
- Veterinary Drug Residues
- Sugars
- Allergens

#### Stakeholder Panel on <u>Dietary Supplements</u>(SPDS)

- Vitamin D
- Aloe Vera Polysaccharides in Dietary Supplements and Dietary Ingredients
- Nonvolatile Ginger Constituents
- Free Amino Acids
- Vitamins K1 and K2
- Ginsenosides in Ginseng
- Echinacea
- S-Adenosyl-L-Methionin (SAMe) in dietary ingredients and finished products

### **AOAC Projects**

- Stakeholder Panel for <u>Infant Formula and Adult Nutritionals</u>(SPIFAN)
  - Biotin
  - Vitamin D
  - 2 and 3-monochloro-1,2-propanediol (2- and 3-MCPD) and glycidyl esters (GE) in infant formula (2- and 3-MCPD and glycidyl esters)
  - Amino Acids
  - Carotenoids
  - Fluoride
  - Folate
  - Galactooligosaccharides (GOS)
  - Vitamin B<sub>3</sub>
- International Stakeholder Panel on Alternative Methods(ISPAM)
- Stakeholder Panel on Agent Detection Assays(SPADA)

### New Important AOAC Methods

- AOAC OFFICIAL METHOD 2014.08: POLYCYCLIC AROMATIC HYDROCARBONS (PAHS) IN SEAFOOD GAS CHROMATOGRAPHY-MASS SPECTROMETRY
- AOAC OFFICIAL METHOD 2014.09, DETERMINATION AND CONFIRMATION OF RESIDUES OF 653MULTICLASS PESTICIDES AND CHEMICAL POLLUTANTS IN TEA GC-MS, GC-MS/MS, AND LC-MS/MS, FIRST ACTION 2014
- You have to be a member to access any AOAC methods
- Link to AOAC website:

http://www.aoac.org/AOAC\_Prod\_Imis/AOAC/SD/SPADA/AOAC\_Member/SH/SPADACF/SPADAM.aspx?hkey=ba02632d-abd0-4a54-be1e-60873eb13a1f

### Thank You

