

Updates on FSMA & Inspections and Lessons Learned



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Renewable Fuels Association

About the Renewable Fuels Association

- ▶ Founded in 1981
- ▶ National Trade Association representing U.S. ethanol producers promoting policy, regulations, research and development for the industry
- ▶ Offices in Washington D.C. and St. Louis, Missouri
- ▶ Leader in legislative efforts of industry
- ▶ Member producers include large bioenergy companies and agribusinesses as well as small farmer-owned co-ops and LLCs



Mission: Drive expanded demand for American-made renewable fuels and bio-products worldwide



Food Safety Modernization Act - Timeline

- January 2011: FSMA signed into law
- October 2013: First version issued (Proposed Rule)
- September 2014: Second version issued (Revised Rule)
- September 2015: Final rule published

Food Safety Modernization Act

Compliance dates for large businesses (>500 employees)

- September 17, 2016 for the CGMPs
- September 17, 2017 for Preventative Controls

Compliance dates for small businesses

- September 17, 2017 for the CGMPs
- September 17, 2018 for Preventative Controls

21 CFR Part 507

Subpart B – Current Good Manufacturing Practice

- 507.14 Personnel
- 507.17 Plant and grounds
- 507.19 Sanitation
- 507.20 Water supply and plumbing
- 507.22 Equipment and utensils
- 507.25 Plant operations
- 507.27 Holding and distribution

21 CFR 507.31 Food Safety Plan

- You must prepare, or have prepared, and implement a written food safety plan.
- One or more Preventive Controls Qualified Individuals (PCQI) must prepare, or oversee the preparation of, the food safety plan.



Components of a Food Safety Plan

Required Components

- Hazard Analysis
- Preventive Controls*
 - Supply-Chain Applied Controls*
 - Process Controls*
 - Sanitation Controls*
 - Other Controls*
- PC Management Components*
 - Monitoring*
 - Corrective Actions and Corrections*
 - Verification*
 - Validation*
 - Verification of Implementation and Effectiveness*
 - Recall Plan*
- Reanalysis
- Implementation Records

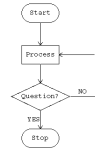
Other Useful Components

- Background Information
 - Food Safety Team
 - Facility Overview
 - Flow Diagram

***Required, when appropriate, if hazard analysis identifies a hazard requiring a preventive control**

Hazard Analysis Process

List Ingredients and Steps/Equipment within the Process Flow (recommended)



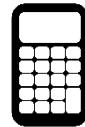
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Assess Severity of Illness or Injury if Hazard were to Occur



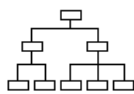
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Determine if the Hazard Requires a Preventive Control



5

Determine the Control for the *Hazard Requiring a Preventive Control*



7



Identify *Known or Reasonably Foreseeable Hazards*



Assess Probability that the Hazard will Occur in the Absence of Preventive Controls



Justify the Classification of the Hazard



Assign a Preventive Control Number (recommended)

8

Hazard Analysis – Required

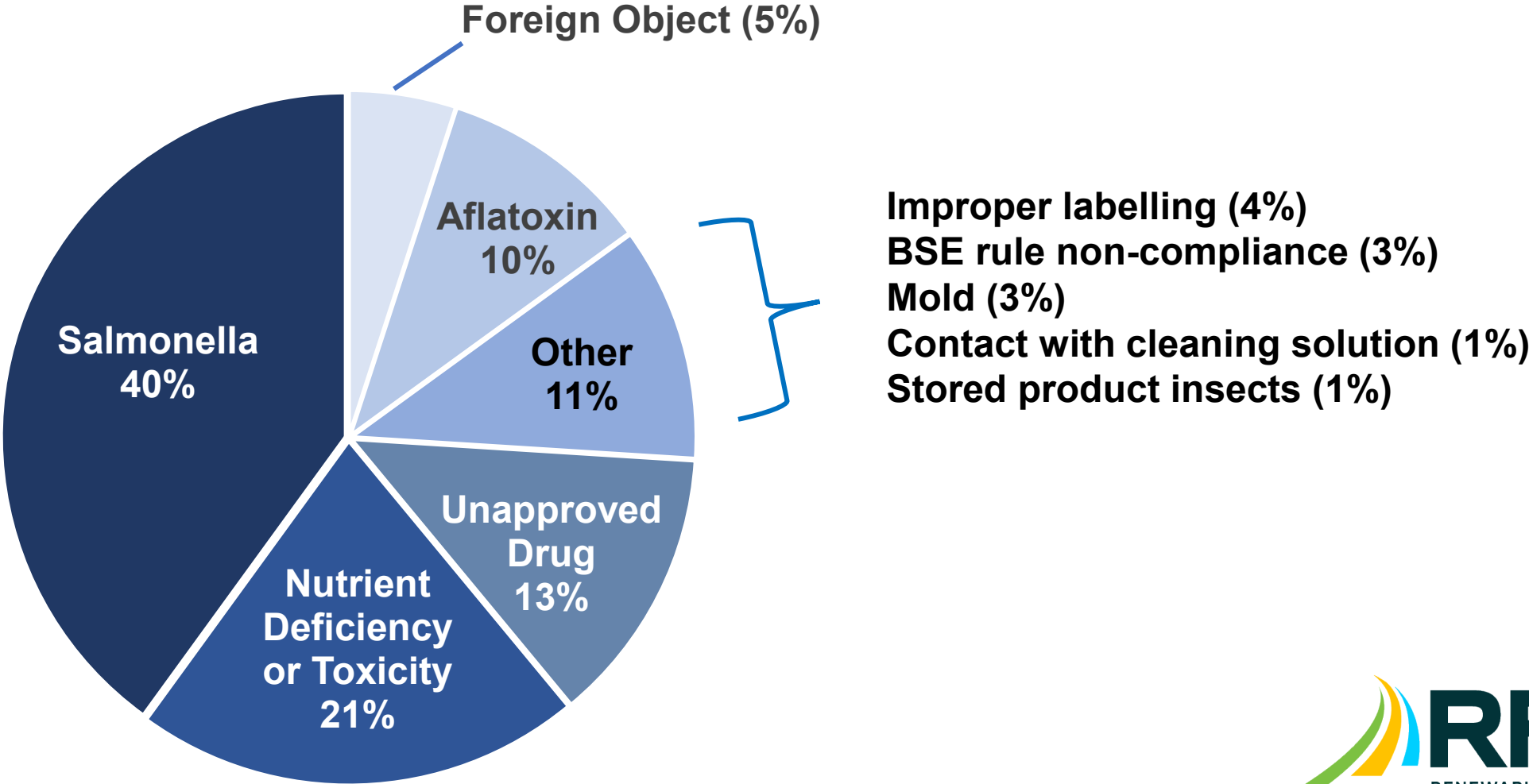
- Drives decision making for determining and controlling hazards
- Hazards considerations for DDGS
 - Physical Hazards
 - Mycotoxins
 - Sulfur

Required Documentation

- Hazard analysis
- Identification of the preventive controls
- Justification for not establishing a preventive control

Reportable Foods Registry Reports

Animal Food



Food Safety Modernization Act Update

- As of September 17, 2018 all ethanol facilities are in compliance with:
 - ✓ CGMPs
 - ✓ Employees have received training and documented
 - ✓ Completed a Hazards Analysis
 - ✓ Have a written Food Safety Plan
 - ✓ If necessary Preventive Controls

Food Safety Modernization Act Update

- FDA Inspectors are now are out inspecting
- CGMP inspections for large and small businesses started in October 2017 and continue
- Inspections for Hazard Analysis and Preventive Controls started Oct 2018 for large businesses and **Fall of 2019** for small businesses

Food Safety Modernization Act Update

- No “findings” yet, just communications
- They will not be able to inspect all businesses
- Continuing to “Educate Before and During” Regulation



Food Safety Modernization Act Update

CGMP Inspections conducted at Ethanol Facilities

- No major concerns were observed
- Minor Findings: *the potential for contamination of animal food during storage*
 - pests
 - foreign materials
 - mold
- Recent inspection scenario...

Food Safety Modernization Act Update

- Inspections are performed by FDA and State inspectors
- FDA working to update inspection program
 - Combining different types of inspections
 - CGMP inspections may be combined with BSE or other inspections
 - Will impact their work planning for both FDA and States

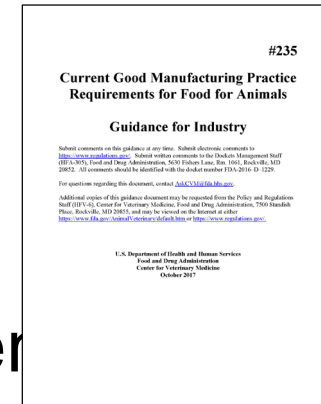
FDA Guidance



- #245 Hazard Analysis and Risk-Based Preventive Controls for Food for Animals - *draft*

<https://www.fda.gov/files/animal%20&%20veterinary/published/CVM-GFI--245-Hazard-Analysis-and-Risk-Based-Preventive-Controls-for-Food-for-Animals.pdf>

- Sanitary Transportation of Human and Animal Food
<https://www.fda.gov/media/108944/download>



- #235 Current Good Manufacturing Practice Requirements for Food for Animals

<https://www.fda.gov/files/animal%20&%20veterinary/published/CVM-GFI--235-Current-Good-Manufacturing-Practice-Requirements-for-Food-for-Animals.pdf>



Contact FDA About FSMA



<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>

- The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies
- Has been operational since September 2015 and providing technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation



Contact FDA About FSMA

- The TAN addresses questions related to the FSMA rules, programs, and implementation strategies
- Inquiries are answered by FDA Information Specialists or Subject Matter Experts
- The TAN staff has compiled answers to common questions
- Routine communication with external TANs, e.g. Alliances (such as the Food Safety Preventive Controls Alliance), are vital for coordination and success.

Food Safety Preventive Controls Alliance

<http://www.iit.edu/ifsh/alliance>

- The Food Safety Preventive Controls Alliance (FSPCA) Technical Assistance Network (TAN) is a network of volunteer Food Safety Experts worldwide providing technical assistance to small and medium-sized businesses to enhance food safety and compliance with the FDA's preventive controls regulations for human and animal food
- The Institute for Food Safety and Health (IFSH) independently manages the Network through the FSPCA
- The FSPCA TAN will provide a way for food industry stakeholders in or outside the United States to submit technical questions to a team of food safety experts
- For training and scientific/technical questions, the FSPCA Technical Assistance Network

<https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network>



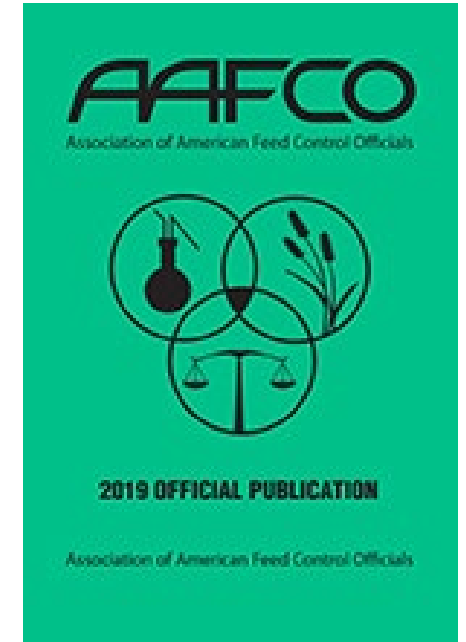
Association of American Feed Control Officials (AAFCO)

Voluntary membership association of local, state and federal agencies charged by law to regulate the sale and distribution of animal foods

AAFCO has no regulatory authority, provides a forum for the membership and industry representation to achieve three main goals:

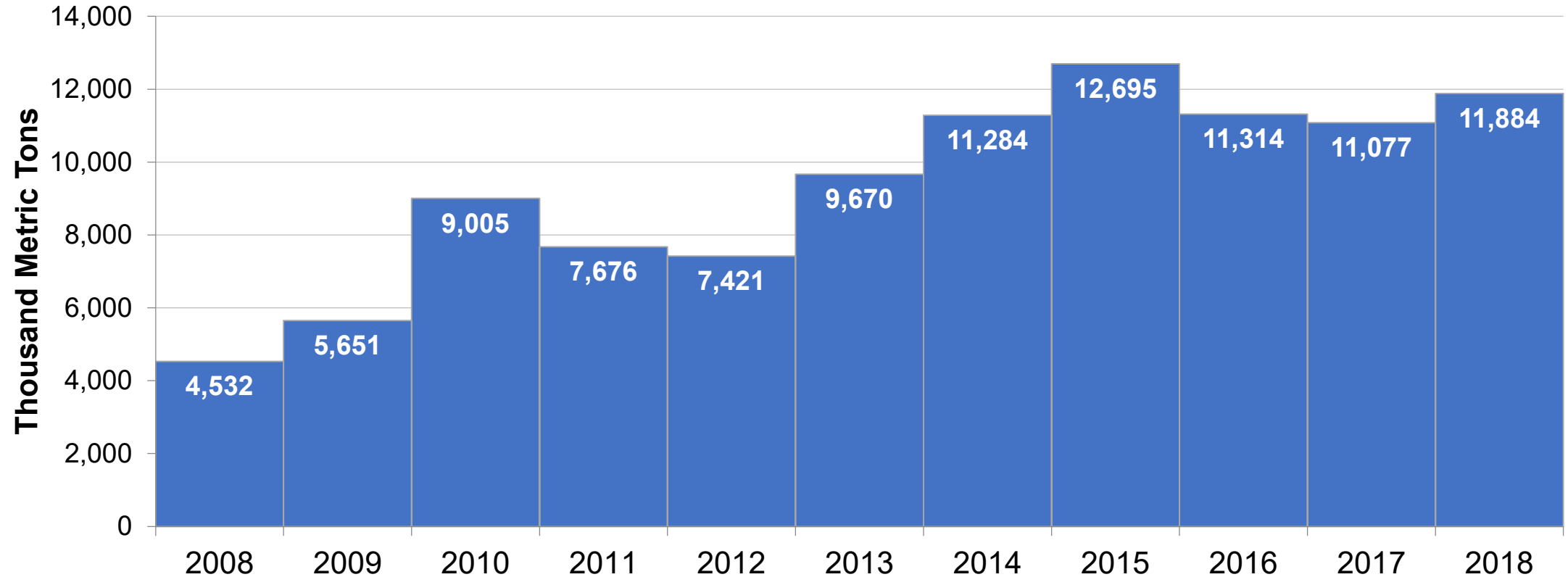
- Safeguarding the health of animals and humans
- Ensure consumer protection
- Providing a level playing field of orderly commerce for the animal food industry

These goals are achieved by developing and implementing uniform and equitable laws, regulations, standards, definitions and enforcement policies for regulating the manufacture, labeling, distribution and sale of animal feeds - resulting in safe, effective and useful feeds by promoting uniformity amongst member agencies.



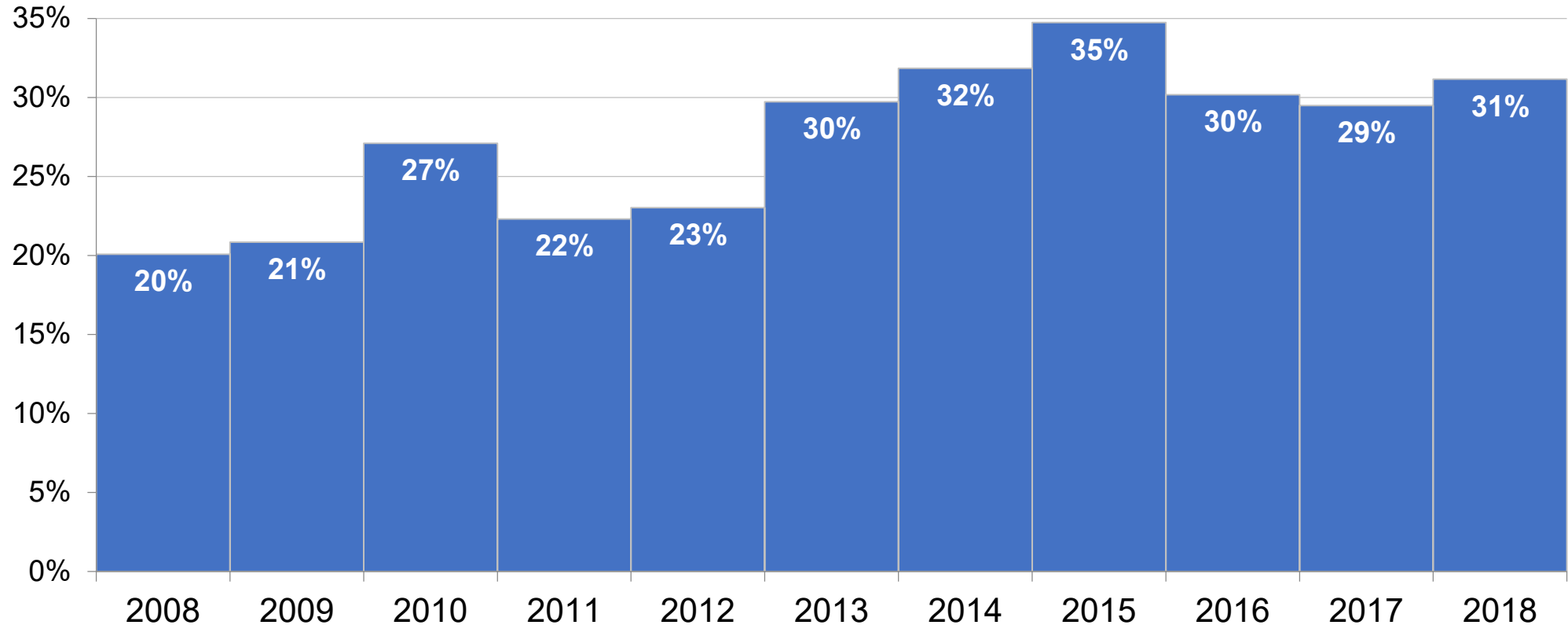
Exports

Annual U.S. Distillers Grains Exports



Exports

Export Share of U.S. Distillers Grains Production



International & CGMP

- Color as an indicator of quality
- Mycotoxins (the analysis and the limits)
- Sulfur
- Sodium
- PCBs
- Dioxin
- Heavy Metals



**Thank
You**