



# Grain and Feed Issues for 2014



## ■ Food Safety Modernization Act

- Signed into law in January 2011
- ♣Biggest change in FDA regulation in 80+ years
  - Hazard analysis, preventive controls (HACCP-based)
  - ► Updated/new CGMP requirements
  - >Written food, feed safety plans
  - Applies to domestic, foreign facilities (exporting products for consumption in U.S.)
  - 50 different sets of regulations, guidance documents
- FDA under court order to issue rules
  - Comment deadlines no later than March 31, 2014
  - Final rule deadlines no later than June 30, 2015

FDA-Proposed Rule Topics	FSMA Deadlines		
	Publishing Proposed Rule	Close of Comment Period	Publishing Final Rule
Produce Rule	Published Jan. 16, 2013	Nov. 22, 2013	June 30, 201
CGMPs and Preventive Controls - Human Food			
Foreign Supplier Verification Programs	Published July 29, 2013	Jan. 27, 2014	
Accreditation of Third-Party Auditors			
CGMPs and Preventive Controls - Animal Feed	Published Oct. 29, 2013	March 31, 2014	
Food Defense/Intentional Adulteration	Published Dec. 24, 2013	March 31, 2014	
Sanitary Transportation	Published	May 31, 2014	

# **Proposed Human Food Rule**

### ■ Major Concerns Raised in NGFA's Comments

- Clarify proposed exemptions from CGMPs and preventive controls for facilities "solely engaged in storage" of raw agricultural commodities other than fruits and vegetables (i.e., grain elevators)
- Urged FDA to exempt packing of raw ag commodities from proposed requirements
- Allow use of appropriate preventive controls commensurate with food safety risk/hazard
- Provide more flexibility in training too prescriptive
- Strongly opposed requirement to submit facility profile
- Opposed mandatory product, environmental testing
- Customer Complaints FDA review should be limited to those pertaining to food safety

# **Proposed Animal Feed Rule**

- Feed mills required to follow new CGMPs and implement HACCP-like preventive controls
- FDA proposed exemption for grain elevators, but definition of "storage" needs to be revised (like in human food rule)
- NGFA comments will urge FDA to:
  - Address "storage" definition
  - Implement realistic, practical and outcome-based CGMP requirements too prescriptive now with long phase-in for
  - Limit scope of preventive controls to feed safety risks that truly meriting rigorous management oversight

    Delay effective date until after CGMP requirements phased in

    Oppose requirement to address "nutrient deficiencies" in hazard analysis

    - Validation provisions problematic Support level playing field
  - Oppose sanitation requirements for animal feed

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## **Proposed Foreign Supplier Verification Program Rule**

- Requires U.S. Importers to Verify Safety of Foreign Foods Intended for Use in U.S.
  - FDA also to establish similar provisions requiring domestic facilities to verify safety of foods received from domestic suppliers
- FDA Proposal Implementing FSMA Requirement
  - Mandates foreign foods be subject to oversight requirements verifying food produced under conditions providing same level of public health protection as required for domestic firms
- NGFA Urging FDA to Exempt Raw Agricultural Commodities from Foreign (and Domestic) Supplier Verification Requirements

## **Proposed Food Defense Rule**

- **Addresses Intentional Contamination of Food** Intended to Cause Large-Scale Public Harm

  \* Applies to domestic, foreign facilities

  - Requires certain facilities to address vulnerable processes in operations
- Proposes to Cover Facilities Engaged in Four "Key" Activities
  - Bulk liquid receiving and loading;
  - Liquid storage and handling;
  - Secondary ingredient handling (the step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient); and
  - Mixing and similar activities
- Proposes to Exempt Animal Feed and Facilities that Only Store Food

# **Proposed Rule on Sanitary Transportation of Food/Feed**

- Proposed Requirements Rail and Truck
  - Shippers required to visually inspect conveyance
  - Information shippers required to provide to carriers Vehicle design and sanitation requirements Use of packaging, isolation and other protective measures Limitations on the use of vehicles
  - Carriers required to supply conveyances meeting shipper requirements and appropriate to prevent adulteration; specify cleaning practices; provide training
  - Information carriers required to disclose to shippers Previous three loads transported by conveyance (waiver) Most recent cleaning of bulk conveyance
  - Maintain records for 2 months

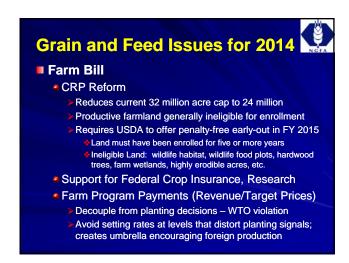
## **Anticipated Compliance Timeframes**

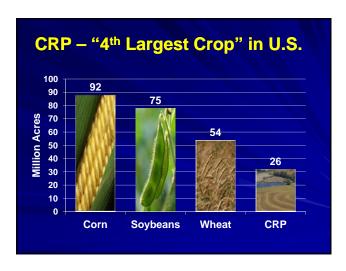
- FDA Final Regulations Likely Won't Be Issued Before Mid-2015 (court-mandated deadline June 30)
- FDA Proposals Provide Additional Time For Compliance After Final Rules Issued
  - One Year: Large Companies (500 employees or more)
  - Two Years: Small Companies (less than 500) employees)
  - Three years: Very Small Companies (to be defined based upon total annual sales of food)

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# What's NGFA Doing? NGFA / AFIA Webinar on Feed Rule – Dec. 11 Promote awareness; respond to questions; encourage industry feedback on proposal Recording now available on demand NGFA's Committees Extensively Reviewing FDA Proposals NGFA Collaborating with Industry Trade Groups in Evaluating Proposed Rules, Drafting Comments PFI, AFIA, NOPA, NRA, GMA, others Extensive Comments Being Submitted on All Proposed Rules

# What's NGFA Doing? Develop Specific Industry Guidance, Compliance Assistance on FDA Final Rules Actively Participating in Food Safety Preventive Control Alliance Comprised of government officials, academia, and industry representatives Goals are to develop FDA-recognized: Standardized hazard analysis and preventive controls training and distance education modules for food/feed industry and regulatory personnel Commodity/industry sector-specific guidelines for hazards and preventive controls





# **Grain and Feed Issues for 2014**



- **Futures Market Performance/Customer Protection – NGFA Priorities** 
  - Put customers first in FCM bankruptcies
  - Optional full segregation of customer accounts - pilot program
  - Explore insurance concept for customer accounts - FIA study underway
  - High-frequency trading
    - Evidence of heightened volatility around release times of USDA reports
    - NGFA continues to seek trading pause
    - CFTC role (e.g., registration, margin requirements)?

# **Grain and Feed Issues for 2014**



- CFTC-Proposed "Customer Protection" Rules
  - Opposed by broad range of ag groups
  - Would change timing of FCMs residual interest calculation - could lead to requirements for users to pre-margin hedge accounts
  - Put more customer money at risk may be double
  - Seek legislative solution in CFTC reauthorization bill
- Big Need CFTC Commissioners with Ag **Backgrounds**

# Grain and Feed Issues for 2014



## **■ CFTC-Proposed Rule on Speculative** Position Limits/Bona Fide Hedging

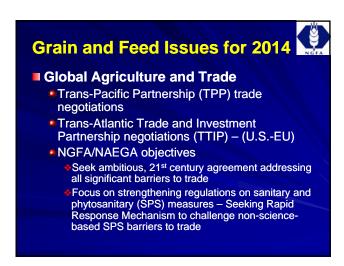
- Would redefine bona fide hedging; omit some common hedging strategies
- NGFA, others objected in comments submitted Feb. 10
- Lengthy review process while three new CFTC commissioners confirmed
- Proposal also would set federal speculative position limits for many commodities - new process for determining ag position limits

# Grain and Feed Issues for 2014



### Transportation

- Water Resources Development Act New momentum to rebuild lock infrastructure!
  - Congress expected to approve in April
  - But missing crucial funding component: Increase in barge fuel user fee
- Major rail proceedings at STB
  - New procedures for challenging unreasonable grain rail rates
  - Competitive switching/access
  - Rail service issues









# Grain and Feed Issues for 2014



- Biotechnology Seeking New Approach to Address Marketability-Related Issues
  - Process launched by ASA, NCGA, NGFA, NAEGA, BIO, ASTA; now consists of 11 national producer, commodity groups
  - U.S. Biotech Crops Alliance Secretariat hired
  - Create "standards" to address market-related disruptions caused by presence in general commodity stream of: Biotech traits commercialized before export market approvals Biotech events with functionally different output traits
  - Four pillars
    - Market risk assessment
    - Market risk management (outcome-based stewardship)
    - Market risk mitigation
    - Market risk responsibility (liability)

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- Biotech International Market Disruptions
  - China
    - Halt to U.S. corn, DDGs shipments caused by presence of unauthorized Syngenta's MIR-162; Chinese regulatory review underway since 2010
    - Largest U.S. corn export market during fourth quarter of 2012 (nearly 4 mmt)
    - ► Utilizes 17% of total U.S. DDGs utilization
    - Syngenta planning aggressive commercialization of Agrisure Duracade - not approved in China