I’m Your Feed Regulator
Here to Help You

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Presented at the
III Global Feed and Food Congress
April, 2010
Cancun, Mexico
Currency of Confidence

The value proposition offered by sound regulatory oversight that is built upon a science-based approach to risk management.
Mission of a Regulatory Agency

Consumer Protection

Vs

Maintaining a Level Playing field
Protecting consumers and enhancing agribusiness through its feed and fertilizer regulatory compliance program, surveillance and monitoring of animal-human health and environmental hazards, and preparedness planning.

Office of the Texas State Chemist

FDA Recall Notices & Alerts

<table>
<thead>
<tr>
<th>Date</th>
<th>Product Type</th>
<th>Short Description</th>
</tr>
</thead>
</table>
Application of a Balanced Scorecard to align resources, data, and internal processes with the OTSC mission that is customer focused.
Mission

Objective #1: Enforce compliance measures to protect consumers and enhance agribusiness.

Measure #1: Percentage of completed corrective actions.

Description: This measure reports the percentage of identified licensing, product registration, labeling, consumer complaints, and sample violations that require corrective actions defined below:
• Licensing refers to firms filing the appropriate forms accompanied by fees to distribute feed and fertilizer products in Texas. All violations involving license require corrective action.

• Samples evaluated for conformance with nutrient guarantees outside three analytical variations will require corrective action.

• Samples containing aflatoxin or fumonisin above the action level that are incorrectly labeled, firms are not licensed with OTSC, do not possess accurate records of distribution of product, do not test corn for aflatoxin, and aflatoxin levels exceed the commercial threshold of 300 ppb require corrective action.

• Firm inspections finding violations involving CGMPs or 21 CFR 589.2000-1 require corrective action.

• All incidents of Salmonellosis accompanied by a *Salmonella* positive confirmation require corrective action.
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Electronic Analysis Reporting System

Please enter a sample number provided to you to view your sample report and then click on "View Results" button below:

Note: Sample number entered must be a 10 digit number. Example: 2007101001

Sample Number: 010101001 View Results

Tracking Sample: Provides the timeline and status information of a sample in our system.

Lab Results: Provides the analytical results for a sample.

*Click on each tab below to view the results

Sample Report: # 2010101001

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Operator</th>
<th>Unit</th>
<th>Lab Result</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRUDE PROTEIN</td>
<td>25.00</td>
<td>0.00</td>
<td>GE</td>
<td>%</td>
<td>25.55</td>
<td>NonViolative</td>
</tr>
<tr>
<td>CHLORTETRACYCLINE</td>
<td>400.00</td>
<td>0.00</td>
<td>GE</td>
<td>gm/ton</td>
<td>374</td>
<td>NonViolative</td>
</tr>
</tbody>
</table>
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OTSC Regulatory Program

- Science based annual work plan
- Science based sample analysis schedule
- Serve as risk managers
- Includes monitoring of human-animal hazards
  - Mycotoxins
  - Microbiological contaminants
  - Heavy metals
  - BSE contract and grant w/FDA

Ben Jones
### OTSC Risk Management Approach

<table>
<thead>
<tr>
<th>Cluster</th>
<th>No. of obs.</th>
<th>Dif. Low Var (%)</th>
<th>Non-Vio Rate (%)</th>
<th>Pert. Rank (%)</th>
<th>Sampling rate (%)</th>
<th>Manufact uring practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>812</td>
<td>65.6 ±16.0</td>
<td>99.9 ±1.2</td>
<td>82.2 ±8.2</td>
<td>30.0</td>
<td>good</td>
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<tr>
<td>2</td>
<td>1636</td>
<td>36.3 ±15.3</td>
<td>99.6 ±3.0</td>
<td>59.9 ±10.6</td>
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<tr>
<td>3</td>
<td>1780</td>
<td>14.9 ±11.0</td>
<td>95.6 ±10.8</td>
<td>31.7 ±11.4</td>
<td>50.0</td>
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<tr>
<td>4</td>
<td>364</td>
<td>150.2 ±79.6</td>
<td>95.6 ±20.1</td>
<td>94.0 ±5.2</td>
<td>65.0</td>
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<tr>
<td>5</td>
<td>181</td>
<td>-11.0 ±38.0</td>
<td>51.4 ±14.2</td>
<td>18.5 ±9.1</td>
<td>97.5</td>
<td>bad</td>
</tr>
<tr>
<td>6</td>
<td>299</td>
<td>-29.0 ±34.2</td>
<td>0.11 ±1.9</td>
<td>5.0 ±3.8</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5072</td>
<td>36.1 ±47.9</td>
<td>90.4 ±25.9</td>
<td>51.3 ±26.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Dif. Low Var, difference of low variance (%); Non-Vio Rate, non-violation rate (%); Pert. Rank, percent rank (%).

Lee, Herrman, Jones 2009
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Generic components of risk analysis

Risk Communication

Risk Assessment
Scientific inputs

Risk Management
Decisions involving Policy and values

Source: FAO - Food Safety Risk Analysis
FDA Proposed New Authorities and Potential Unintended Consequences

- Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories
- Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products
- Authorize FDA to Accredit Highly Qualified Third Parties for Food Inspections
- Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective
- Provide FDA Enhanced Access to Food Records During Emergencies
- New data sharing a collaboration with states

Food Protection Plan
An integrated strategy for protecting the nation’s food supply
Regulations Impact on the Market

- Association of American Feed Control Official Model Bill
- FDA pursuit of self-affirmed GRAS versus letters of no-objection
- Feed Industry HACCP
  - Required in the EU
  - Voluntary in the US
AAFCO Model Bill

Model Bill and Regulations

Officially Adopted by
Association of American Feed Control Officials
And Endorsed by
American Feed Industry Association
National Grain and Feed Association
Pet Food Institute
GRAS and Letter of No Objection

- GRAS before 1958 that FDA has generally recognized as safe
- FDA is in the process of developing a self-affirmed GRAS guidance
- The self-affirmed GRAS will replace the current practice of issuing a letter of no objection. During the Atlanta Feed Regulators Meeting hosted by IFIF in 2010, Dan McChesney from FDA-CVM acknowledged that Letters of No Objection can distort trade.
Hazard Analysis and Critical Control Point

*Europe Feed Hygiene Regulation*

**Hazard analysis and critical control points (HACCP) system**

1. Feed business operators carrying out operations other than those referred to in Article 5(1) shall put in place, implement and maintain, a permanent written procedure or procedures based on the HACCP principles.
Verification Program for a Voluntary HACCP Plan

- Provides clarification on how to apply HACCP principles when manufacturing feed. This represents the first such document in the global feed industry and can be applied to the multitude of HACCP schemes and certification systems developed by feed trade associations in the US, Canada, and Europe. The program also provides the basis upon which competent authorities can provide third party audits “upon request” by firms that do not subscribe to commercial auditing services.