



Wi-Fi

Renaissance_Conf
Savery@2019

Regional Annual Meeting of the IBB and the NBB

FSMA Training Update
IBB Food Safety Program

Wednesday, September 18, 2019



Introductions

- Name
- Plant name and location
- What you would like out of the session?

Biodiesel Food Safety Program

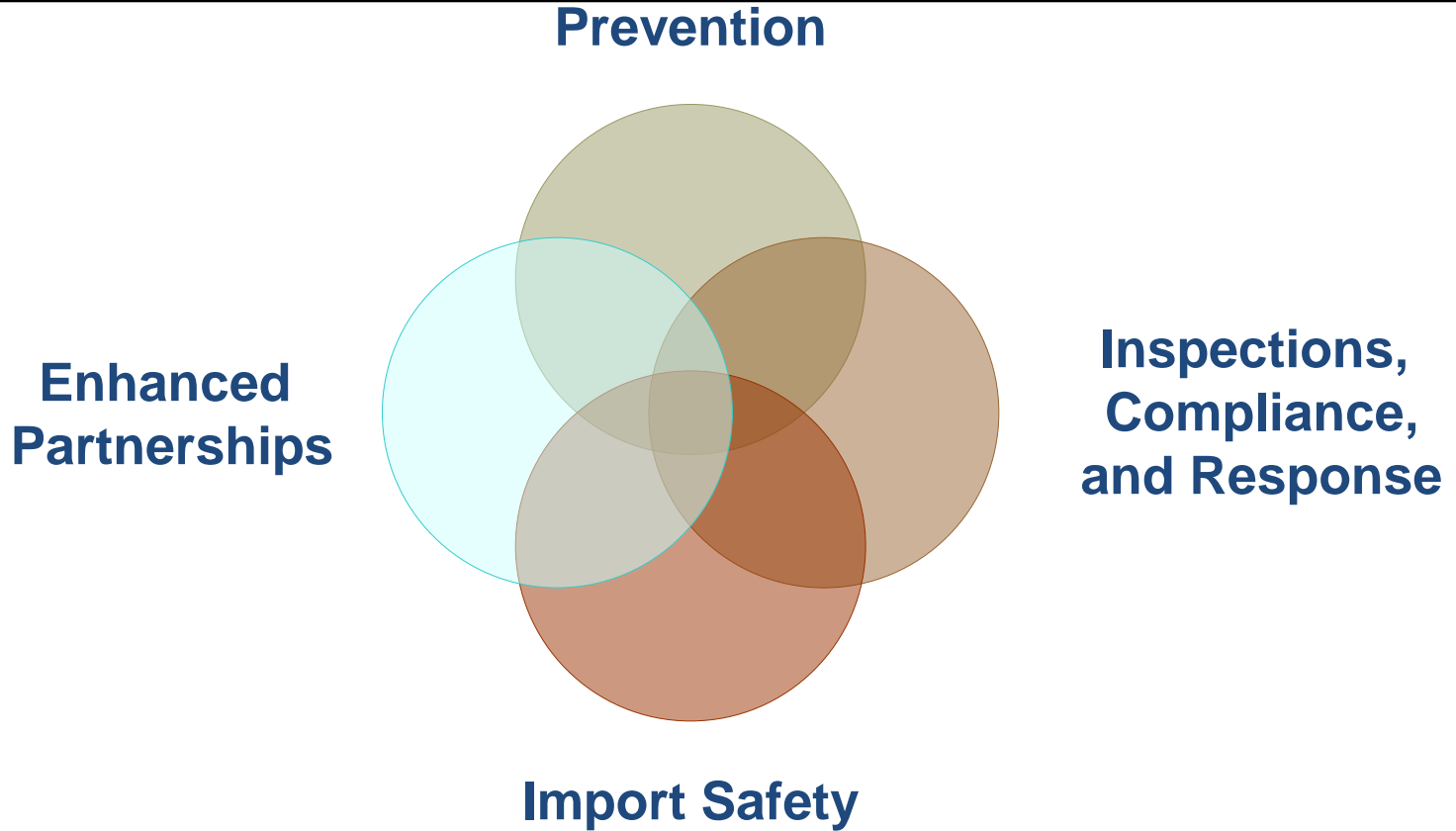




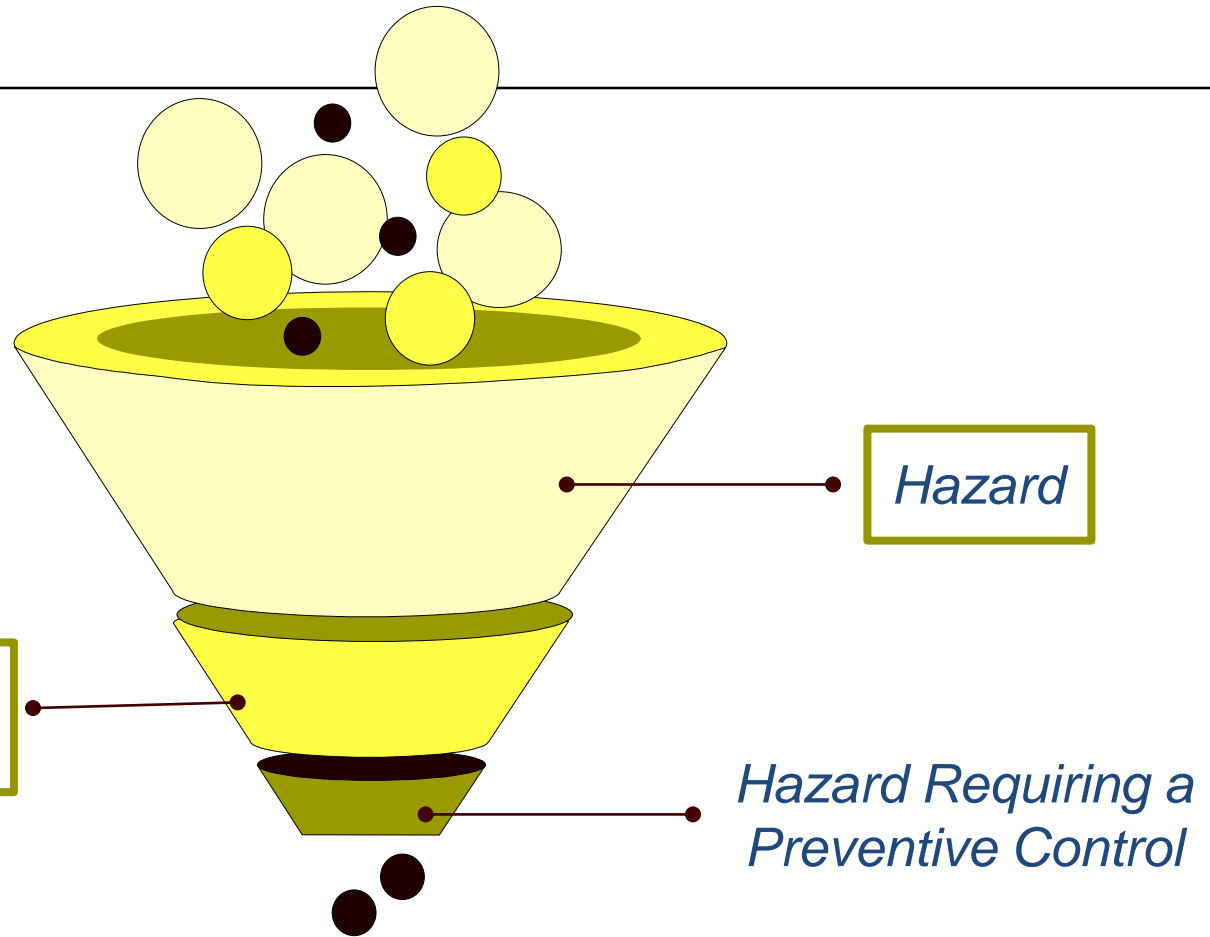
Food Safety Modernization Act

- 21 CFR Part 507 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (HARPC)
- The FDA program is compared regularly to: HACCP – Hazard Analysis Critical Control Points. Certification Program for Food Safety

FSMA Snap Shot



Hazard Analysis Process





Steps to Complete Food Safety Plan

- ❑ Assemble Team
- ❑ Describe Product and Distribution
- ❑ Describe Ingredients and Process Aids
- ❑ Construct Process Flow
- ❑ Verifying Process Flow
- ❑ Conduct Hazard Analysis



Seven Principals of Food Safety

- ❑ Analyze Hazards
 - ❑ Physical, Chemical, Biological
- ❑ Identify Critical Control Points (CCP) or Preventive Controls (PC)
- ❑ Set critical limits for each point
- ❑ Develop procedures to monitor
- ❑ Have corrective action
- ❑ Establish procedures to verify
- ❑ Have effective recordkeeping



Prerequisite Programs (PRP)

- ❑ Training
- ❑ Personnel Practices
- ❑ Premises, Facilities & Equipment
- ❑ Good Manufacturing Practices (cGMP)
- ❑ Housekeeping (Sanitation) & Pest Control
- ❑ Receiving, Storage & Transporting
- ❑ Trace and Recall
- ❑ Supplier Control
- ❑ Hazardous Material Handling

What Are the Requirements of Records?

- Records must
 - Be kept as original records, true copies, or electronic record
 - Contain actual values and observations
 - Be accurate, indelible, and legible
 - Be created concurrently with performance of the activity
 - Be detailed as necessary
- Records must include
 - Information adequate to identify the plant or facility (name and location)
 - Date and, when appropriate, time of the activity
 - Signature or initials of the person performing the activity
 - The identity of the product and lot code, if any, when appropriate

Iowa Biodiesel Food Safety Guidance – Provides overall instructions

- Step 1 – Assemble Food Safety Team
- Step 2 – Describe Product and use
- Step 3 – Describe Ingredients and Process Aids
- Step 4 - Construct Process Flow
- Step 5 – Conduct Hazard Analysis
- Step 6 – Establish Records and Documentation
- Templates and training materials included
- Compliments a BQ-9000 Program but not needed

(PCQI) Preventive Controls Qualified Individual(s)

Must oversee:

1. Preparation of the Food Safety Plan
2. Validation of the preventive controls
3. Determination that validation is not required
4. Review of records
5. Reanalysis of the Food Safety Plan
6. Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production
7. Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days
8. Determination that reanalysis can be completed, and additional preventive controls validated as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production

FSMA is here. Where is your plant at on implementation?





INTERNAL AUDITS

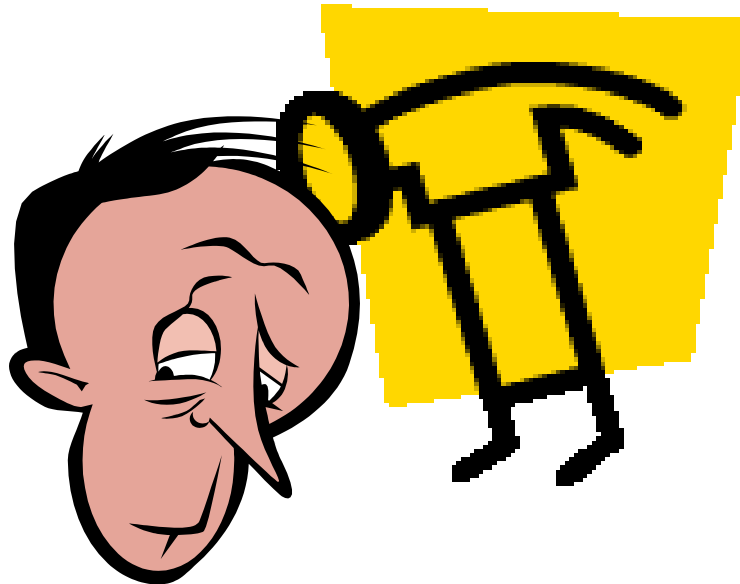


What is an Audit?

A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

An Internal Audit

Should not be used to determine blame and fault and should not result in employee discipline





Basic Steps for an Audit

- ❑ Scheduling the audit
- ❑ Planning the audit
- ❑ Opening Meeting
- ❑ Audit the areas
- ❑ Auditors document findings
- ❑ Final Audit Report
- ❑ Closing Meeting
- ❑ Creating the audit file



Internal Audit Helpful hints

- ❑ Macro Flow Chart of the Process – basic flow from beginning to end
- ❑ Understand the Process – what are the documented information we are looking for
- ❑ Type of audit – forward or backward audit
- ❑ What will be product or service to audit – decide on the item we will be following



Guides to help with audits

- ❑ HACCP checklist
- ❑ Safe Feed Safe Food Checklist
- ❑ FDA Guidelines
- ❑ cGMP Guidelines
- ❑ BQ-9000 Internal audit training
- ❑ PCQI training



BREAK



FDA UPDATE



FSMA Implementation Update

- Reported by the FDA at the AAFCO FSMA Workshop on August 4, 2019
- FDA continues to “Educate Before and During” regulation

Preventive Controls for Animal Food 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

Business Size	<u>Subpart B</u> Current Good Manufacturing Practice	<u>Subpart C</u> Hazard Analysis and Risk-Based Preventive Controls
All Others	Sept. 19, 2016	Sept. 18, 2017
Small Businesses (< 500 FTE)	Sept. 17, 2018	Sept. 17, 2019
Very Small Businesses ($< \$2.5$ million/year)	Sept. 17, 2019	Sept. 17, 2020



FSMA Implementation Update


- ❑ cGMP inspections are being conducted at all business sizes
- ❑ Routine PC inspections started in October 2018 for “large” businesses
- ❑ Routine PC inspections at “small” businesses will begin in fall 2019; however are conducting some “for cause” inspections in FY 19

Type, Number and Percent of 483's issued. (Data reported up to mid-July 2019)

□ CGMP (domestic)	177	12%
□ CGMP (foreign)	17	18%
□ CGMP (by State)	323	14%
□ PC (by FDA domestic)	87	28%
□ PC (by FDA foreign)	13	15%
□ PC (by State)	21	24%
□ Sanitary Transportation	39	8%
□ FSVP	7	29%

FDA Inspections: Common Inspection Citations:

- ❑ Failure to identify/implement a preventive control
- ❑ Hazard analysis
- ❑ No written food safety plan
- ❑ Food safety plan not done/overseen by PCQI
- ❑ Failure to establish/implement corrective action procedures
- ❑ Failure to validate preventive control
- ❑ Failure to conduct a reanalysis



FDA Inspections: Be prepared to justify your hazard evaluation

1. The feed stock of the Biodiesel
2. The condition, function, and design of the facility and equipment;
3. Materials used for processing
4. Transportation practices;
5. Manufacturing/processing procedures;
6. Lot identification and labeling activities;
7. Storage and distribution;
8. Intended or reasonably foreseeable use;
9. Sanitation, including employee hygiene
10. Any other relevant factors such as leased storage, weather factors, contractor labor



FDA Inspections – Continued

Be prepared to respond to requests for information or records that are not expressly required by the regulations

- Customer complaints files
- Lists of top customers and suppliers
- Business volume information
- Organizational charts
- Table of contents for QA manuals

Report by National Feed and Grain Association



What's it all about?

CONFIDENCE

Of Customers

CONFIDENCE

Of Government Agencies

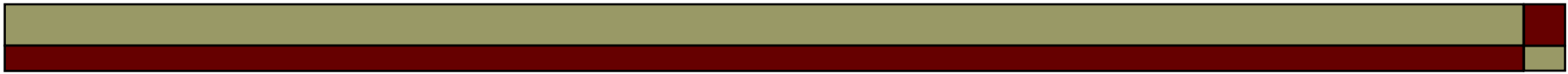
CONFIDENCE

Of Auditors

Thank you! Questions?

Learn more at IowaBiodiesel.org







Verification

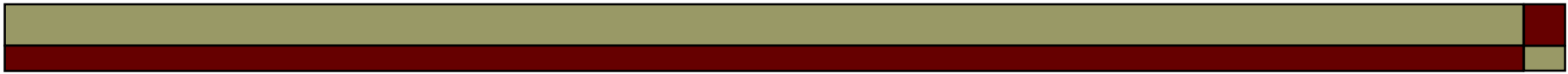
Validation

Verification that
Monitoring is
Being Conducted
as Required

Verification that
Appropriate
Decisions are
Being Made about
Corrective
Actions as
Required

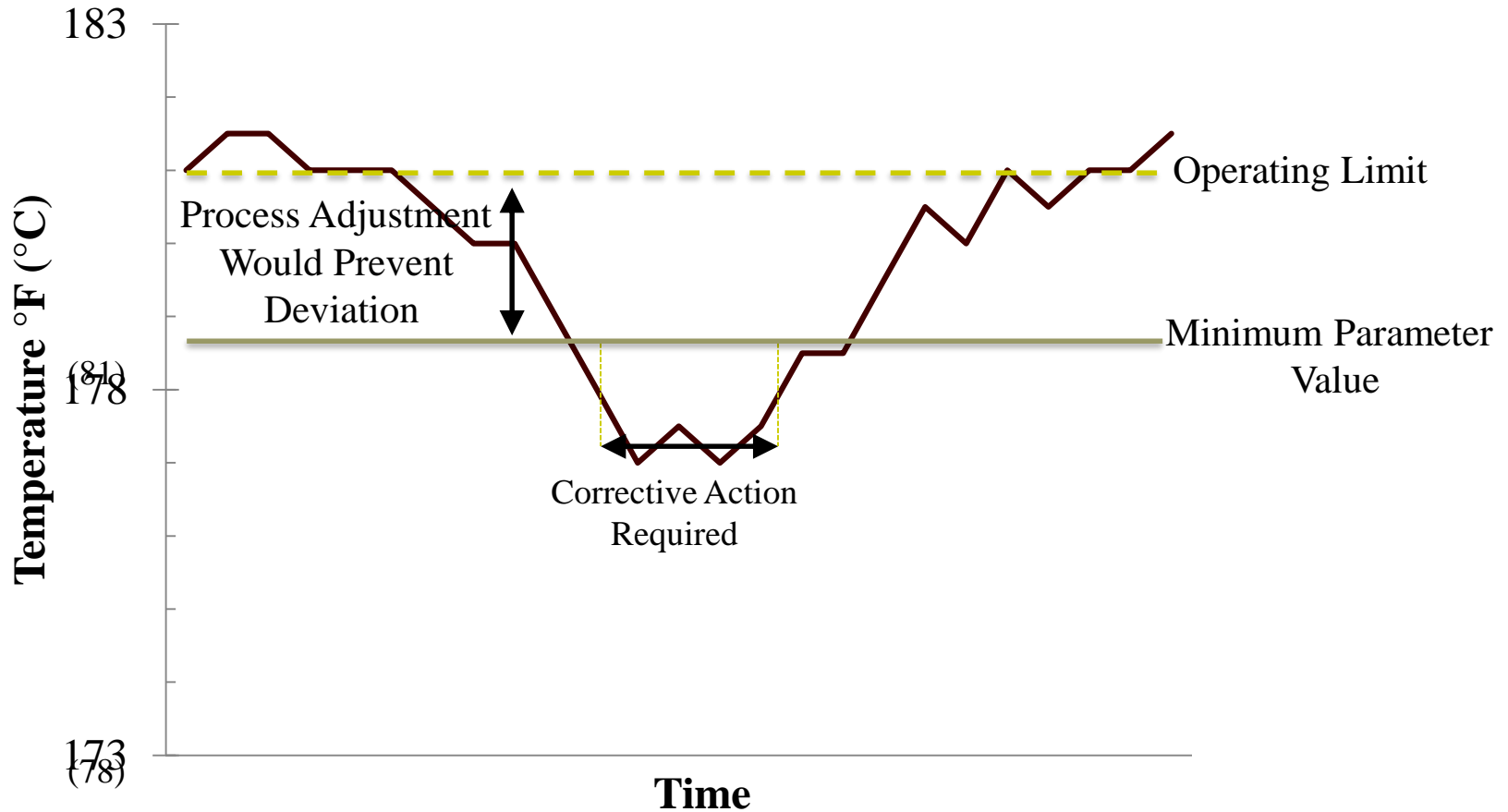
Verification of
Implementation
and Effectiveness

Reanalysis of
the Food
Safety Plan

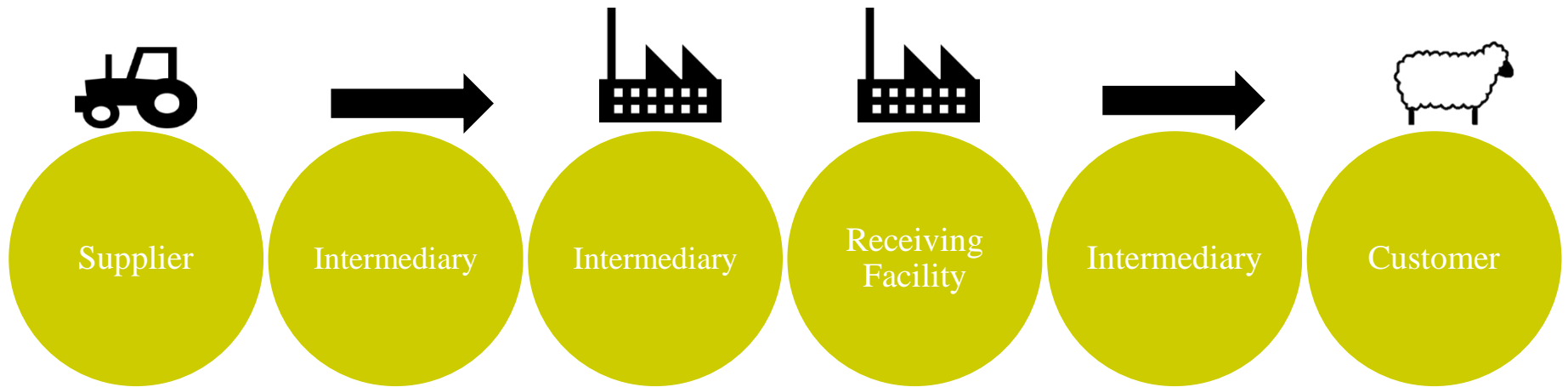


Operating Limit Example

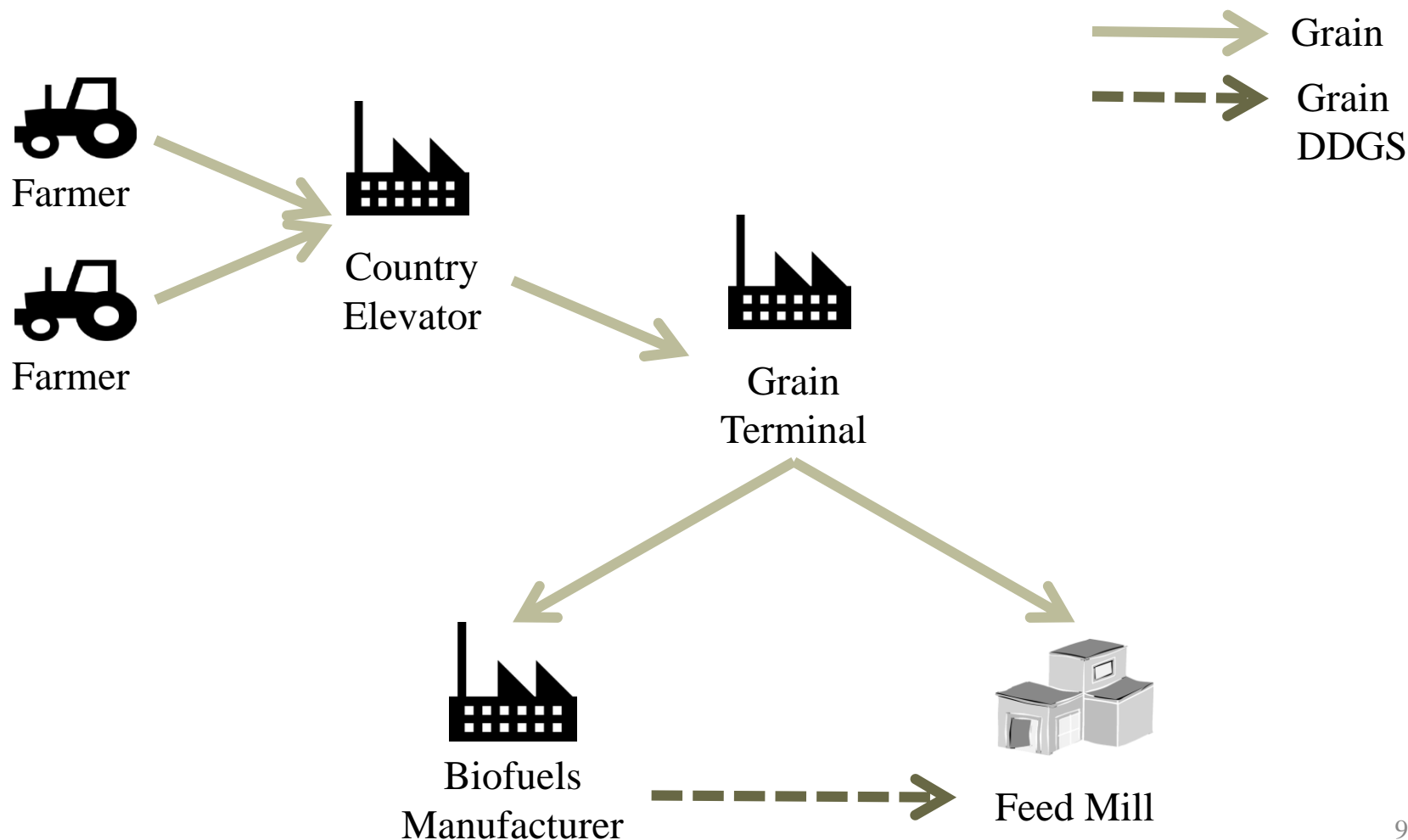
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Types of Supply Chains



Who is the receiving facility's supplier?





What Does it Cost?

Criteria to receive thumb drive & discounted fee schedule for desk and field audits:

Iowa Biodiesel Board Member Plants

- ❑ One-time upfront fee - \$3,000
- ❑ Sign Liability Waiver
- ❑ Maintain membership

Non-Member Plants

- ❑ One-time upfront fee - \$6,000
- ❑ Sign Liability Waiver



What Does it Cost?

Consulting Options:

- 1 day off-site review/Desk Audit: \$815
- 2 days on-site at facility/Field Audit: \$3,100
- Option to renew every three years (review required by law)

Services provided by Degart Global.