

2010 Education Program 3-A Annual Meeting





Major Opportunities & Challenges in Food Safety & 3-A's Role

Milwaukee, Wisconsin

May 18, 2010



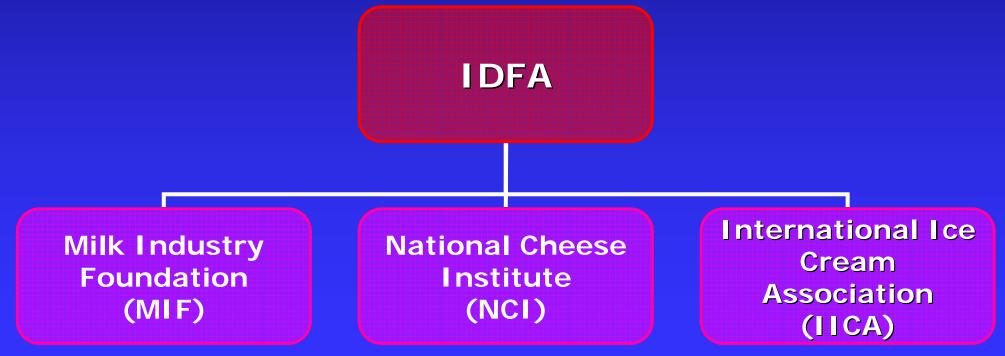
Allen R. Sayler Vice President International Dairy Foods Association



Who Does IDFA Represent



- IDFA represents dairy processing, manufacturing and marketing companies and their suppliers, with a membership of 530 companies representing a \$90-billion a year industry
- Represent 85% of all dairy products produced and manufactured in U.S.





IDFA What Do We Offer Regulatory Affairs Legislative and Economic Communications, **Education and Meetings** International Trade Administrative





International Dairy Foods Association Milk Industry Foundation National Cheese Institute International Ice Cream Association



IDFA Communications



- IDFA's Website: <u>WWW.IDFA.ORG</u>
- Weekly Electronic News Magazine (members only) subscribe by emailing News Update

newsupdate@idfa.org

• Weekly Electronic Food Industry Business Magazine (everyone)

http://www.smartbrief.com/idfa/index.jsp

IDFA SmartBrief

Sign up for IDFA's FREE DAIRY BUSINESS E-NEWSLETTER!

Sustainability Workshop, April 14-15, 2010, Chicago, IL



- **Advanced Dairy and Juice HACCP Workshop**, April 27-29, 2010 Ontario, CA
- **Dairy Cost Accounting Workshop**, May 11-12, 2010, Rosemont, IL
- Milk and Cultured Dairy Products Symposium, May 24-26, 2010, Rosemont, IL
- Washington Conference (Become a Driv Lobbie of a Day) June 16-17, 2019, Washington, Editory Show
- SQF Practitioner Ser Stop, 14 e 2 630, 20, 10 icago, IL

Advanced Dairy & Juice HACCP Workshop, October 6-7, 2010, Chicago, IL





The voice of the industry



Classes of Membership:

- **Processor:** Converts milk and whey solids into finished marketable products at a U.S. plant.
- Associated Processor: A further processor milk solids. (e.g., agglomeration) •
- International: Processors or further processors located outside the U.S. •
- Affiliate: Manufacturers, distributors or suppliers of equipment, materials or • services to the industry.
- Utilization: End-users of milk solids.
- Individual: Qualifying industry individuals.

Membership in ADPI is open to all companies involved in the manufacture of dairy products. Applications for membership must be approved by **ADPI** and all applicants must agree to conform to the organization's bylaws and make all payment of dues as set forth therein.

WHEY PRODUCTS, DRY MILK PRODUCTS, EVAPORATED & **CONDENSED PRODUCTS AND CHEESE** 6



The voice of the industry



The American Dairy Products Institute provides a variety of services to members, representing them in governmental affairs, consumer affairs and product standards of identity.

- Our goal is to provide our membership with complete information about the industry from processing through utilization.
- To achieve this objective, ADPI provides the following standards :
 - Dry Milks—ADPI Bulletin 916, "Standards for Grades of Dry Milks Including Methods of Analysis"
 - Whey Products—ADPI Bulletin W-16, "Whey & Whey Products Definitions, Composition, Standard Methods of Analysis"
- Additionally, we organize several member committees and co-host the American Dairy Products Institute/American Butter Institute Annual 7 Meeting.



The voice of the industry



Website Address for Additional Information: http://www.adpi.org/Home/tabid/36/Default.aspx

Current 3-A User/Processor Stake in 3-A

- \$12,000 per year in dues
- Chair of the 3-A Board of Directors
- Chair of the TPV Coordinating Committee
- 6 members on 3-A Steering Committee/Consensus Body
- 2 members on 3-A Interpretations committee
- Approx. 20 members on 14 3-A Working Groups



Emerging food safety environment in the United States: Processor Perspective

- Current status: Messy
- Consumer Views: Too Many Failures
- New Federal Legislation: Certainty
- New Federal Regulation: Certainty



FOOD SAFETY REALITIES

- Ground beef always??
- Undeclared Allergens always??
- Black Pepper & Other spices
- Cleaning chemicals-school milk
- Hydrolized Vegetable Proteins (HVP)
- Cookie Dough
- Tomato/Peppers
- Melamine in Dairy
- Melamine in Pet Food
- Spinach
- Ready-to-eat foods that required heating by consumer









Food Safety Recalls - 2009

- Georgia Plant Will Recall Every Single Peanut Product Made in Last Two Years 3/25/09
- Salmonella Worries Prompt Pistachio Recall 3/30/09
- FDA Warns of E. coli Risk From Nestle Toll House Cookie Dough 6/19/09
- Plainview Milk Products Expands Dry Milk Salmonella Recall 7/7/09



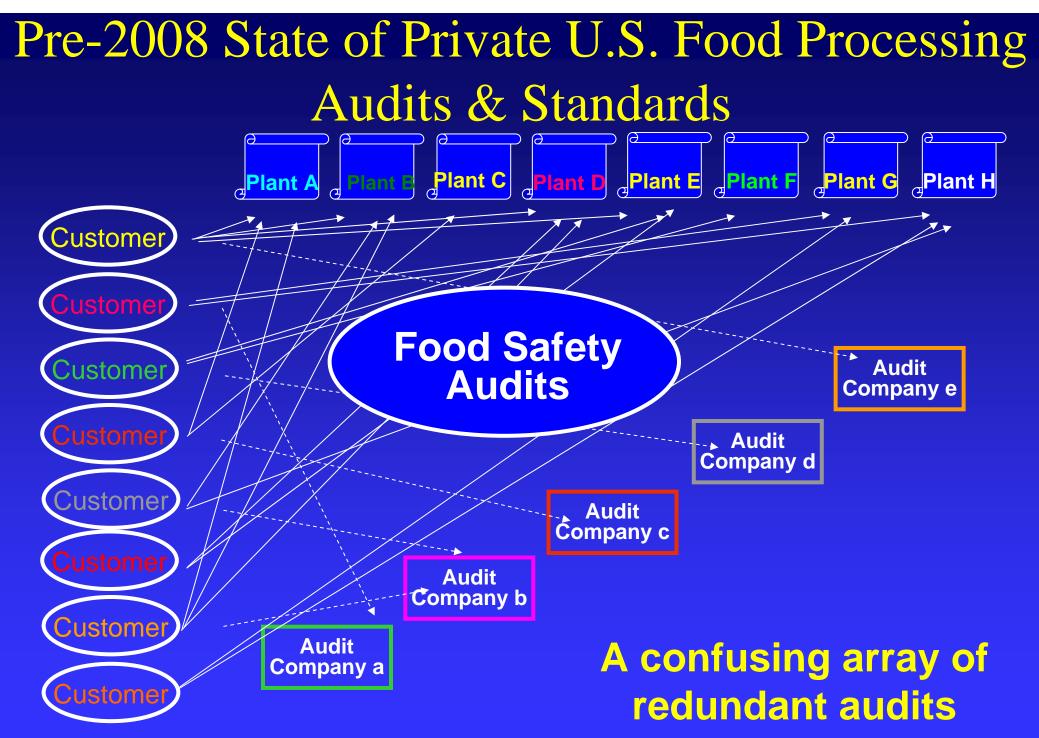


http://www.fda.gov/safety/recalls/default.htm

How & Why - Dairy Industry

- Cleaning Chemicals in School Milk
- Pasteurized Products Listeria
- Infant Formula E. Sack.
- Allergen Recalls
- Raw Milk Cheese Listeria
- Raw Milk ecoli O157H7, listeria





In 2010, what are the top 3 food safety issues.

- Biological risks / Microbial Safety traditional
- 2. Weakest Link: Suppliers of Ingredient, food additive, packaging & equipment
- Inability of U.S. food industry to consistently deliver safe and high quality foods driving consumers toward unprocessed foods



In 2020, what will be the top 3 food safety issues.

- 1. Biological risks / Microbial Safety new emerging pathogens or existing microbes with new lethality
- 2. Substantial government over-regulation of the food industry and its suppliers
- 3. Over-extended supply chain stretching around the globe

Will there be new food safety solutions?

Is 3-A equipped to provide new food safety solutions?



In 2020, Food Safety will continue to be a key consumer issue.

- Food Safety
- Food prices
- Health and Wellness
- Environment
- Food Security



Consumers

- Consumers expect safe wholesome food every time

- Consumers are looking for more natural, less processed and sustainably produced
- Consumers utilize the internet and social media to obtain information since they distrust government agencies & the "big" food industry
 - Raw Milk Movement one of many examples



New Federal Laws & Regulation

- Development of new regulations

- New Federal Food Safety Law Very likely
- Updated FDA GMPs
- Aggressive FTC on advertising to children



How does this impact EHEDG, DIN or 3-A SSI?

Need to address....Concerned with "open records" concept of handling normal testing data. The regulatory professionals understand how this information is to be used. The general public and "sensationalistic" media will not understand how this information is used, and will come to very wrong and potentially damaging conclusions. These conditions are leading us to the direction of having no "forgiveness" in the results. Every company will need to be "perfect" every time samples are taken and tested. Do we in 3-A believe that our equipment designs can allow perfect swabbing and testing results, every time?



IDFA "Guess" at FDA Changes to cGMP

1. Employee Training Plan

 Require appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products.

2. Written Equipment Sanitation Procedures

 Written procedures that define the scope, objective, management responsibility, monitoring, corrective action, and record keeping





Anticipated Changes to cGMP

3. L. mono. Environmental Monitoring Plan (could be expanded to include Salmonella)

- Written environmental monitoring plan for *Listeria monocytogenes*.
- Must include microbiological monitoring of the production and packaging environment as appropriate.
- Processors would be required to maintain the records documenting the effectiveness of the program and response to positive results



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Anticipated Changes to cGMP

4. Allergen Monitoring Plan

 Processor responsible for a written allergen monitoring plan addressing the eight major food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans)

5. Temperature Monitoring

- Provide performance-based operation temperature criteria and remove all specific time-temperature requirements in the existing GMPs
- National and state regulations that specify processing times & temperatures are "safe harbor" and no validation is required.





Anticipated Changes to cGMP

6. Records Retention and Access

- Maintain certain "critical records" and that these records be made available for review and evaluation by FDA investigators in order to confirm that a firm is operating in compliance with the GMP regulations.
- No mandatory access to written plant programs. Records that document management of required GMPs would be accessible by FDA.

Final cGMP update regulation issuance expected no later than end of 2010





- Gives FDA greater regulatory powers food supply
- Increase the frequency of FDA inspections of food processing plants based on risk
- Expands FDA's traceback capabilities for when outbreaks
- FDA mandatory recall authority
- Requires food facilities to have safety plans in place in order to mitigate hazards
- Registration and user fees



• Administrative detention

 Lower legal standard from "credible evidence or information indicating [that the article of food] presents a threat of serious adverse health consequences or death" to "reason to believe [that the article of food] is adulterated or misbranded

• Preventative Controls

 Required the hazard analysis to identify preventive controls - recall and traceback procedures, supply chain management. Give FDA authority to evaluate the effectiveness of these plans and to establish/enforce²⁵



- Notification/Mandatory Recall
 - Notification of recall to FDA
 - Mandatory recalls if a voluntary recall is refused
 - Standard for mandatory recall would be tied to if food product "serious adverse health consequences or death."
 - Collect fees defray cost related to recall activities up to \$20 million or reinspection \$25 million
- User fees
 - Flat registration fee \$500 \$2,000 per facility in registration

• Third party certification



- FDA would accredit foreign governments, states and third parties to certify food facilities - audited 4 yr
- Import restrictions
 - Deny entry to any import facility or foreign government refuses to consent to an investigation where food from the facility or country is linked to a foodborn illness outbreak or is otherwise adulterated
- Records Access
 - Access to copy records during an inspection "needed to assist" in determining whether food is adulterated or misbranded." without written request

3-A Roles & Responsibilities

- Improve credibility of program
- Develop many more standards
- Expand into other food sectors
- Develop strong and more integrated relationships with other international standards bodies.



odEngineering AGAZINE FOR OPERATIONS AND MANUFACTURING MANAGEMENT Emerging food safety environment the United States: Processor

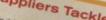
PUMPS & VALVES

Innovative Ideas for Dairy Processors



FOOD SAFETY RUTTER'S DAIRY

April 2010



Suppliers Tackle Food Safety While dary processors are revamping their ins to ensure stricter food safety es, suppliers also are getting into the ng with a range of equipment de e nearly any dairy plant For instance, Fred Weber, I

April 2010

Food

no cross-contamination of one of the major food allorgens, including milk, eggs, tree nuts, wheat, peanuts and soybeans. It is also an important indicator that all traces of od residue, which could provide a m g possible path Weber Scientific also dev

Using Zones of Control To Improve

Food Safety

Hixson webinar on Food Safety.

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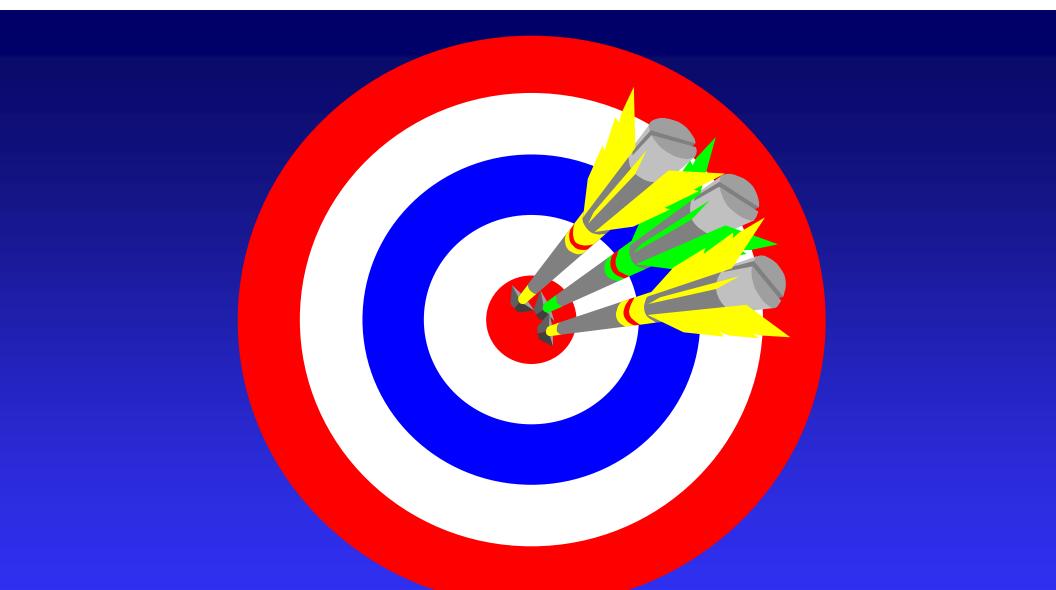
future

AND REPORT: EQUIPMENT CLEANABILITY EMERGES AS FOOD SAFETY FLASHPOINT

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Who Has the First Question???



Regulatory Approach to 3-A

Wisconsin Department of Agriculture Glenn A. Goldschmidt

Wisconsin Guidelines Used

- ATCP 80.12
- 3-A Sanitary Standards & Accepted Practices
- WI Design and Construction Guidelines For Dairy Equipment
- FDA Milk and Milk Product Equipment Guide
- USDA Guidelines For The Sanitary Design And Fabrication Of Dairy Processing Equipment

Each State is Different

- Some States Adopt 3-A Into Regulation
- Some States Reference 3-A In Regulation
- Some States Adopt PMO
- Some States Simply Utilize 3-A As Guidance

FDA

- References 3-A In PMO- "Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance."
- Individual Guidelines for Construction
- Equipment Review Committee AMDERC

USDA

- USDA Guidelines For Construction
- Participates In 3-A
- CFR Does Call For Conformance With 3-A
- Does Not Accept 3-A <u>Only</u> And Will Review All Equipment
- Use of USDA Guidelines For Construction When A Standard Is Not Written

TPV Program

- Third Party Verification Is Needed
- Strive To Gain Uniformity
- RAN Program Has Been Used
- Changes To Equipment Without AN RAN
 - Report
 - Alleged
 - Nonconformance
- Problems

United States vs. Europe

- Many Differences
- EHEDG
- Coming Together
- Distance Is A Problem
- Language Barrier Is A Problem

Wisconsin Experience

- Department Reviews All Equipment
- Does State That Equipment Meeting Standards Is Sanitary
- Has Found Problems With TPV
- Has Found Problems With Equipment Design
- Not All Equipment Is Written Into Standards

Improvements Needed

- Strengthen TPV Program
- Continue to Add Uniformity
- Add Manufactures Of Equipment Not Just Promoting Specific Ideas
- Add Standards





3-A and Global Hygienic Design Lou Beaudette/Admix and David Seckman/FPSA May 18, 2010



- Founded in 1912, FPSA has focused on facilitating collaboration between equipment and other technology suppliers and the food and beverage industry
- Today, FPSA has over 450 member companies that supply products for every link in the supply chain from receipt of raw materials and ingredients through delivery to the retail sector



- FPSA members provide solutions to all segments of the global food industry
 - •Meat
 - •Dairy
 - •Bakery/Snacks
 - Prepared Foods

- •Fruit & Vegetable
- •Beverage
- Confectionery
- Frozen Foods



Over the years, FPSA's tradeshows have put a spotlight on innovative manufacturing solutions and served as a resource where food industry professionals know they can find experts to deal with their company's most critical issues



2010-CHICAGO



In addition to our trade show, FPSA helps to link suppliers and customers throughout the year in a variety of formats and forums, including the FPSA Conference, the Food Processing Buyer's Guide and the Annual Operation's Conference



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Online Nielsen Food Safety Poll:

- > 90% said food safety affects their decision about where to shop
- > 70% said it is the food manufacturer's responsibility to provide safe food
- > 34% of individuals trust the media most when a food scare arises
- > 33% government
- > 23% food manufacturer
- > 10% retailer



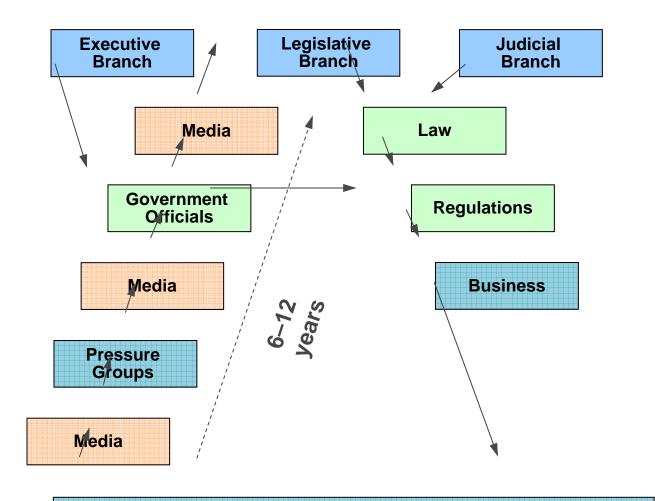
USDA Food Safety & Inspection Service (USFSIS@govdelivery.com)





- Beef Trim Products
- Ready to Eat Deli Meat Products
- Beef Stew
- Mini Pretzels
- Buffalo Style Chicken Salad
- Imported Prosciutto
- Crumbled Pork Sausage

U.S. Public Policy Process



General Public

Source: Handbook of Strategic Public Relations and Integrated Communications.



Three Key Legislative Proposals:

- H.R. 2749
- > S. 510
- > S. 2819



H.R. 2749: "Food Safety Enhancement Act"

- Creates an up-to-date registry of all food facilities serving American consumers: Requires all facilities operating within the US or importing food to the US to register with FDA annually
- Generates resources to support FDA oversight of food safety: Requires payment of an annual registration fee of \$500 per facility that would generate revenue for food safety activities at FDA



- Prevents food safety problems before they occur: Requires foreign and domestic food facilities to have safety plans in place to identify and mitigate hazards. Safety plans and food facility records would be subject to review by FDA inspectors and third-party certifiers
- Increases inspections: Sets a minimum inspection frequency and domestic facilities. Each high risk facility would be inspected at least once every 12 months; each low risk facility would be inspected at least once every 18 months to three years; and, each warehouse would be inspected at least once every five years. Refusing, impending or delaying an inspection is prohibited



- Improves traceability: Significantly expand the FDA's traceback capabilities in the event of a foodborne illness outbreak. Directs the Secretary of HHS to issue traceback regulations that enable HHS to identify the history of the food in as short of timeframe as practicable, but no longer than two business days
- Expands laboratory testing capability: Requires the FDA to establish a program to recognize laboratory accreditation bodies and to accept test results only from duly accredited laboratories



- Provides strong, flexible enforcement tools: Provides the FDA new authority to issue mandatory recalls of tainted foods. Strengthens penalties imposed on food facilities that fail to comply with safety requirements
- > Advances the science of food safety: Directs HHS to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses. Mandates greater coordination between federal, state and local agencies



- Enhances the FDA's ability to administratively detain tainted food products
- Allows HHS to prohibit or restrict movement of harmful food products: If HHS determines there is credible evidence that an article of food poses an imminent threat, then the movement of that food can be restricted
- Provides protection for whistleblowers that bring attention to important food safety information: Prohibits discrimination against any employee in retaliation for assisting in any investigation
- Grants the FDA new authority to subpoena records related to possible violations



S. 510: "Food Safety Modernization Act"

- > Hazard analysis and preventive controls: Requires all facilities that manufacture, process, pack or hold food to have in place risk-based preventive control plans to address identified hazards and prevent adulteration, and gives FDA access to these plan and relevant documentation
- Inspection: Requires FDA to inspect all food facilities more frequently, including inspections of high-risk facilities at least once a year and inspections of other facilities at least once every four years



- Mandatory Recall: Gives FDA the authority to order a mandatory recall of a food product if the food will cause serious adverse health consequences or death and a company had failed to voluntarily recall the product upon FDA's request
- Administrative Detention: Gives FDA the authority to administratively detain any food that is misbranded or adulterated under the Food, Drug and Cosmetic Act
- Increases FDA Resources: Increased funding for the FDA's food safety activities through increased appropriations and targeted fees for food facility reinspection, food recalls, and the voluntary qualified importer program



S. 2819: "The Processed Food Safety Act"

Requires processors of food to certify that food product has undergone pathogen reduction treatment or that the corporation has tested and certified that the ingredient(s) contain no verifiable trace of pathogens

Processors of poultry and beef provide an accurate description of the product they package



Senator Feinstein: "The Processed Food Safety Act puts the responsibility for food safety back where it belongs. This legislation protects consumers and keeps our food safe. And it will let consumers know that their health is more important than the financial interests of the food industry."

Senator Feinstein further added that"..... this act *will* force companies to produce safe foods."



3-A and Global Hygienic Design



Global Hygienic Design

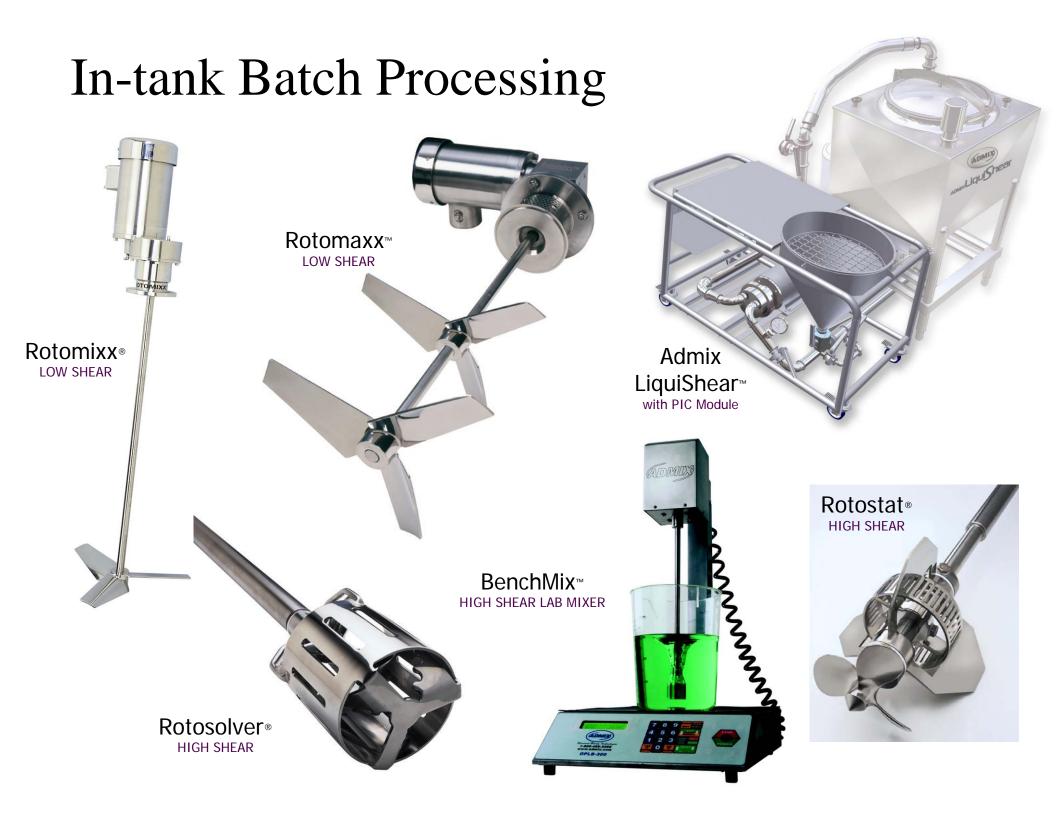
An Equipment Supplier Perspective

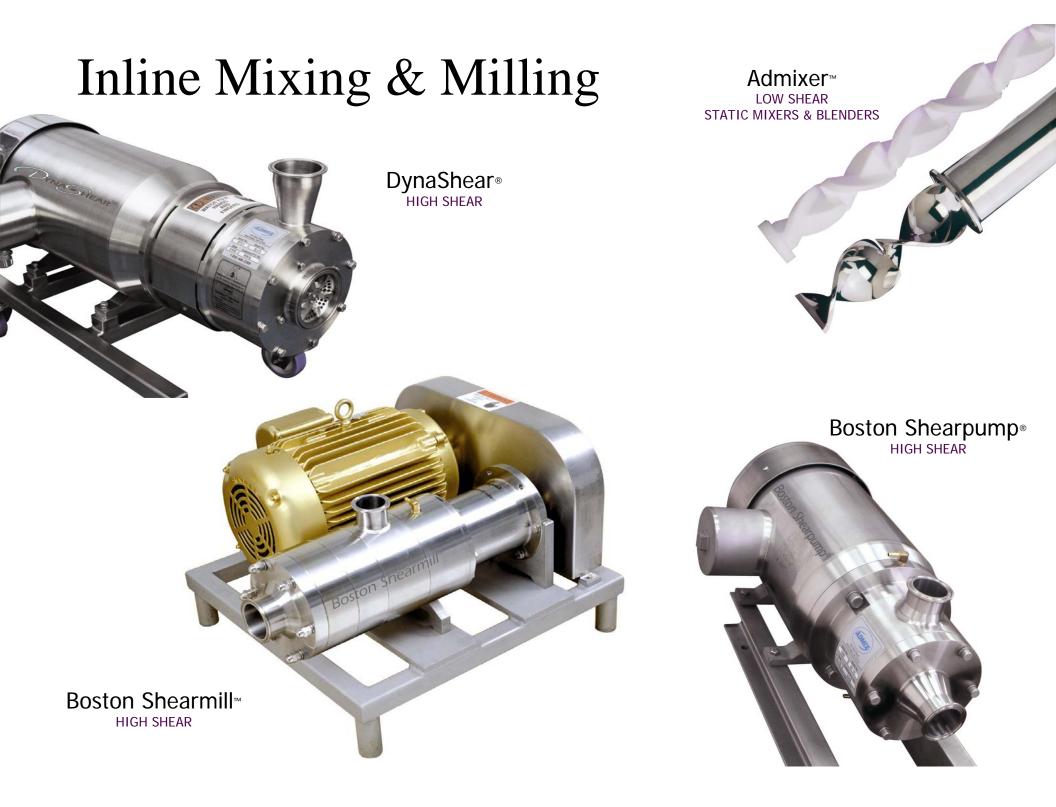




Company Background

- Design & manufacture Sanitary mixing and blending equipment with particular emphasis on wetting out and dispersing powders and solids into liquids
- Provide 14 product lines with primary focus on Food and Pharma processing
- Equipment used in batch processing, inline continuous processing, as well as powder induction
- Carry multiple 3A SSI symbols covering Blending Equip (35-03), Inline Mixers (36-01), Shear Mixers (73-01)









Design Challenges

- Bullet proof gearboxes, bearing frames and motors not within product zone All SS best
- Use mechanical seals where feasible (new standard in progress)
- Make sure end user installs and operates as directed (i.e. 4" stand off clearance, maintain flush for seals)
- Can be easily disassembled where CIP and COP not always possible





Global Connection Challenge

- Primarily North American based sales, with goal to increase European sales from 5 to 15% of sales over 3 years.
- Have an affiliate in Europe where we have begun cross manufacturing
- This creates concerns as to whether 3A conformance will comply with EHEDG and CE and vice versa





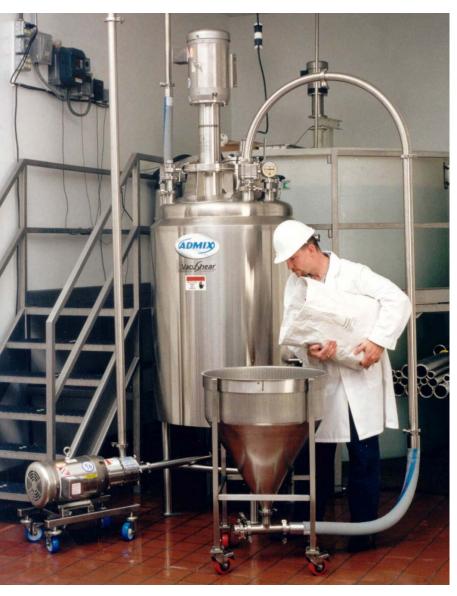
Other Hygienic Issues

- As a major supplier to the meat and poultry processing industry, we need keen awareness of and compliance with all guidelines from USDA, AMI, NSF and other organizations
- Meat & Poultry also presents unique challenges from high concentration of brine (salt), as well as condensation from machines running hot within a cold environment.
- Skids that may contain from 2 to 5 pieces of process machinery need to be inspected as a whole to ensure total compliance

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Future Needs

- Self certification on any level does not cut it 3rd party inspection critical for success with more training and enforcement
- Processors within all food segments, not just dairy, need to specify equipment manufactured to 3A SSI standards
- Harmonization of global as well as industry standards will make compliance easier, more accessible, and less expensive for processors