



Wednesday, October 21
11:00 am–12:30 pm

311 Ensuring Safety and Quality of Products Manufactured in China

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Senior Vice President and Chief Scientific and Regulatory Affairs Officer
Grocery Manufacturers Association

Bruce Clark

Principal
Marler Clark LLP

Joan Menke-Schaenzer

Global Chief Quality Officer
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Scott Rickman

Associate General Counsel
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Faculty Biographies

Bob Bracket

SVP & Chief Scientific and Regulatory Affairs Officer
Grocery Manufacturers Association

Bruce Clark

Principal
Marler Clark LLP

Joan Menke-Schaenzer

Joan Menke-Schaenzer is global chief quality officer of ConAgra Foods in Omaha, NE. She leads programs to create a world-class foundation for quality and food safety through the standardization of best practices throughout ConAgra.

Prior to joining ConAgra, Ms. Menke-Schaenzer was vice president of food safety and defense at Wal-Mart Stores, Inc., in Bentonville, Arkansas. She led the creation of worldwide quality, food safety and food defense programs and standards, all designed to protect the public while mitigating risks to Wal-Mart and its brands. Prior to that she was with Kraft Foods, Inc., in Northfield, Illinois. She last served as vice president of Kraft Foods North America Quality and Food Safety. During her tenure at Kraft, her accomplishments included leading the development of worldwide quality and food safety programs and policies through the Phillip Morris Worldwide Quality Council and the development of the company's crisis management/quick response team.

Ms. Menke-Schaenzer earned a BS from the University of Wisconsin in Madison, Wisconsin.

Scott Rickman

Scott T. Rickman is associate general counsel at Del Monte Foods in San Francisco. Del Monte is one of the country's largest and most well-known producers, distributors and marketers of premium quality, branded and private label food and pet products for the U.S. retail market. Mr. Rickman has manages Del Monte's litigation and environmental compliance programs and also provides legal counsel to the company's manufacturing facilities on a variety of matters, including agricultural issues and general business and contract law.

Prior to joining Del Monte, Mr. Rickman was an associate with the San Francisco law firm of Gordon & Rees. He has also been an associate with the law firm of Varnum, Riddering, Schmidt & Howlett in Grand Rapids, Michigan. He served for six years in the U.S. Marine Corps and was selected as Marine of the Year for the Marine Barracks, London, England.

He is a frequent speaker on issues relating to food law and litigation

Mr. Rickman received a BA from the University of Michigan and graduated cum laude from the University of Wisconsin Law School.

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Import Safety In the News

Consumers are alarmed by the headlines

"Bogus Toothpaste Shows Need For Import Scrutiny"

"Pet Food Recall Raises Questions About Imported Food Safety"

"US Calls On China To Improve Export Safety"

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A Recent Example

Melamine in pet food case:

- Wheat gluten manufactured in China was contaminated with melamine
- Caused widespread product recalls when the contaminated wheat gluten was used to make pet food in the U.S.
- Eventually 90 class actions were filed against the pet food industry
- Companies ultimately settled for \$25 million
- U.S. importers subsequently pled guilty to federal criminal charges
- Chinese response

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Other Incidents

- Recent problems with Chinese products:
 - Melamine in milk, baby formula and pet food
 - Toys coated with lead paint
 - Contaminated pharmaceuticals
 - Diethylene glycol in toothpaste
- Although affected products include both food and other consumer products, this panel will focus on food

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U.S. Response

- Heightened concern for products made in China
- Consumer Product Safety Improvement Act (2008)
- Food Safety Enhancement Act (not yet passed)
- FDA issued guidance for third-party certification
- FDA studying economic adulteration controls
- FDA traceability pilot projects
- Action Plan for Import Safety

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**Ensuring Safety and Quality of Products
Manufactured in China**

An Industry and Regulatory Perspective

Robert E. Brackett, Ph.D.
Senior Vice President and Chief Science and
Regulatory Affairs Officer
Grocery Manufacturers Association

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An Era of Globalization

- Globalization: Everything has changed!
- Implications for food safety are uncertain, although concerns remain.
- Food safety bar is being raised.

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International Food Safety Issues

- Recognition of food safety as a priority issue.
- Differing standards and/or changing food safety regulations.
- Obligation to base national standards on international norms.
- Obligation to use risk-based food safety standards.
- Right for countries to take measures and choose their own level of protection balanced with the requirement that measures applied only to the extent necessary to protect human/animal/plant health.
- Obligation of countries to consider equivalence.

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Industry Responsibility

"The food industry is ultimately responsible for the safety of its products."

*Pamela G. Bailey
President and CEO, GMA*

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Prevention, Partnership, Planning

Supply Chain Initiatives To Improve Food Safety

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Product Recall Modernization

- High-profile nationwide recalls have exposed weaknesses in the nation's food safety net.
- Product recalls are complex and multi-faceted events requiring expeditious action by a variety of stakeholders.
- Modernization of the recall process through greater collaboration among manufacturers, retailers and government agencies will reduce the amount of time it takes to identify and remove recalled products from the marketplace.

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Accredited Third Party Food Safety Certification

- Important part of the food safety net.
- Can play a critical role in efforts to continually improve the safety of our food supplies.
- Food companies routinely retain third party auditors to assess conformity to ensure they meet or exceed standards, and to identify steps to continually improve food safety.
- Congress and the Food and Drug Administration (FDA) are considering ways by which third party certification bodies can supplement FDA efforts to improve food safety.

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Modernization and Implementation of Good Manufacturing Practices (GMPs)

- Recalls and consumer advisories highlight the need to modernize and strengthen our nation's food safety system to meet the challenges of a global food supply.
- GMPs help ensure the safe and sanitary manufacturing, processing, and holding of food for human consumption.
- Many of the recent foodborne disease outbreaks have been associated with Good Manufacturing Practice (GMP) failures.
- FDA has formed a working group, held public meetings, sought input on GMP modernization.
- Industry has actively engaged and is providing input to FDA at every opportunity.
- Industry is working with allied stakeholders to develop education and training programs to foster widespread implementation of existing GMP regulations and will aggressively pursue the timely adoption of and training on new GMPs as soon as they are issued.

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Economically Motivated Adulteration

"Contamination thought to have been intentionally introduced for economic gain."

*Randall Lutter, Ph.D.
Deputy Commissioner for Policy*

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Recent Cases

- Melamine in food
 - Added to infant formula & dairy to enhance perceived quality.
 - Added to flour intended for pet food to enhance protein content.
- Diethylene Glycol
 - Foods contaminated from substitution with toxic syrup.

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Strategy for Prevention

- Food industry has actively addressed economic adulteration for over 20 years.
- Industry has continual had to adjust strategy, refine methods, and share intelligence to stay ahead of unscrupulous operators.
- FDA is looking for new ways of predicting risk, based on new risk factors associated with economically motivated adulteration.
- Industry must practice due diligence to assure that products received from suppliers meet required regulatory, legal, and contractual standards of safety.

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Supply Chain Management

- Focus on internal procurement procedures
- Focus on the supplier
- Focus on process used at supplier
- Traceability

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Summary

- International trade in foods and agricultural products will continue to increase.
- It is critical that industry and regulatory agencies acknowledge the challenges associated with globalization.
- It is even more critical that government and industry work together to address the challenges.

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**Ensuring Safety & Quality of
Products Manufactured in China**


An Industry Perspective

Joan Menke-Schaenzer
Global Chief Quality Officer

- Leading branded, value-added company focused on delivering sustainable, profitable growth
- Serving millions of consumers through **Grocery, Retailers, Restaurants & other Foodservice** establishments
- **98% of American households** have at least one ConAgra Foods product in their pantry, refrigerator or freezer
- **\$11.6 Billion in Net Sales** – Fiscal 2008
- **25,000 Employees**
- Headquarters in **Omaha, Nebraska**

Food & Ingredients

Consumer Foods



Gary Rodkin, ConAgra Foods CEO

**“Nothing is More Important
than the Safety and Purity
of Our Food”**

**China Connections –
In Country Qingdao Gilroy Foods & Flavor**



China Connections – Direct Imports to U.S.

“Boots on the Ground Model”

- Team of Nationals –
Shanghai, Beijing & Shenzhen
Office
- Dehydrated Vegetables
- Continued Growth Expected

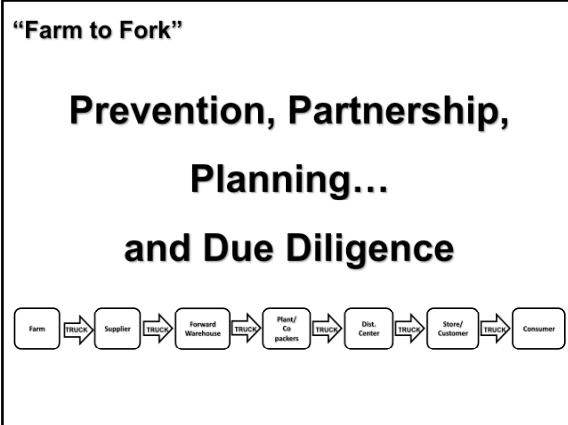
China Connections – Importers & Brokers

Small Volumes Currently

Careful Growth Planned

Store
Rate

Fees
Customer
DC Rate





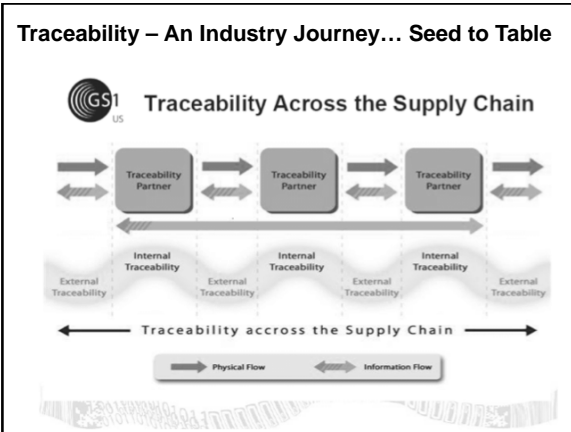
Accredited 3rd Party Food Safety Certification

PROS

- Common expectations, standards and audit approach
- Enables continuous improvement of Food Safety Systems
- Confidence in sourcing and Food Safety for the consumer

CONS

- Announced
- Limited effectiveness for uncovering "bad actors"
- A challenge for small suppliers today



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Ensuring Safety and Quality of Products Manufactured in China

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By
Scott Rickman
Del Monte Foods

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New Importer Security Filing Requirements

- As a result of the SAFE Port Act
 - Requires Importers and Carriers to electronically submit additional info on cargo before it is brought into the U.S. by vessel.

• Mfg. (or supplier) name, address	• Seller name, address
• Buyer name, address	• Ship-to name, address
• Container stuffing location	• Consolidator name, address
• IOR number	• Consignee number
• Country of Origin	• HTS number

Plus: Vessel Stow Plan and Container Status Message

- Info must be provided electronically 24 hours prior to loading

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FDA Amendments Act of 2007 (FDAAA)

- Requires the Secretary of Health and Human Services to promulgate within two years of the date of enactment these standards:
 - Ingredient standards and definitions
 - Processing standards; and
 - Updated standards for labeling that include nutritional and ingredient information
- Reportable Food Registry
 - Capturing of relevant information to trace adulteration of animal feed and human food through the supply chain
 - Utilizes the same standards as Class 1 recalls. Requires company to notify FDA
- Mandatory Reporting
 - Reporting is mandatory and must be done no later than 24 hours after company discovers its product is adulterated or must be recalled

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Shift in Industry Strategy

Industry Groups have issued safety standards:

- The Toy Industry Association partnered with the American National Standards Institute (ANSI) to create a safety assurance program for toys
- GMA April 2008 Food Supply Chain Handbook
- Other GMA initiatives: food recall portal, encouraging use of internationally certified auditing firms, and formation of 60-company coalition to provide GMP education
- In February 2008 Wal-Mart announced that certain suppliers must be certified by the Global Food Safety Initiative. Certification requires that all goods must be audited by licensed food safety auditors.

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Action Plan for Importer Safety

Create new and strengthen existing safety standards

- Identify and Promote best practices in companies and their suppliers
- Written policies and procedures defining commitment to safety
- Communicate new and strengthened standards throughout the supply chain
- Standards need to be documented, maintained and continuously improved

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Action Plan for Importer Safety

Import Safety requires Cross Functional Effort

- Contract Manufacturing (including Suppliers!)
- Logistics and Transportation
- Customs Compliance
- Quality Control
- Legal
- Safety and Security
- Human Resources
- Risk Management

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Improving your legal protection

Jurisdiction and dispute resolution:

- You can't sue them if you can't serve them
- U.S. jurisdiction
- International arbitration

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Improving your legal protection

Collecting damages:

- You can't collect from them in China, but you do have alternatives
- Have producer post a letter of credit
- Have producer add you as an additional insured, with an insurer selected or approved by you
- Back-stop with your own insurance

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Other Issues

- Right to Audit and Inspect:
 - Require producer to conduct internal self-assessments and audits
 - Reserve right for third-party audits
 - Require timely correction of deficiencies
 - Require verification
- Traceability:
 - Of which ingredients?
 - How far back in the chain?
 - Supply chain fragmentation issues

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FDA Bioterrorism Act (BTA)

- BTA expanded FDA's authority with respect to foods through several specific areas of new FDA regulatory and administrative power including:
 - Requiring registration of food facilities with FDA (foreign and domestic)
 - Prior notice for all imported food shipments under FDA authority
 - Record keeping requirements for food facilities
 - FDA detention of food where credible evidence may present a threat of adverse health consequences
 - Debarment of food importers for violations related to food importation; and
 - One up and one back traceability

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“Ensuring the Safety and Quality of Products Manufactured in China”

William Marler
 Managing Partner
 Marler Clark LLP

Civil Litigation – A Tort – How it Really Works

- Strict liability
 - It is your fault – Period!
- Negligence
 - Did you act reasonably?
- Punitive damages
 - Did you act with conscious disregard of a known safety risk?

Strict Liability for Food – a Bit(e) of History

“... a manufacturer of a food product under modern conditions impliedly warrants his goods... and that warranty is available to all who may be damaged by reason of its use in the legitimate channels of trade...”

Mazetti v. Armour & Co.,
 75 Wash. 622 (1913)

Who is a Manufacturer?

A "manufacturer" is defined as a "product seller who designs, produces, makes, fabricates, constructs, or remanufactures the relevant product or component part of a product before its sale to a user or consumer..."

RCW 7.72.010(2); see also *Washburn v. Beatt Equipment Co.*, 120 Wn.2d 246 (1992)

The Legal Standard: Strict Liability

- The focus is on the product; not the conduct
- You are liable if:
 - The product was unsafe
 - The product caused the injury

STRICT LIABILITY IS LIABILITY *WITHOUT* REGARD TO FAULT.

The "China Problem"

- China shipped goods worth a total of \$288 billion to the U.S. in 2006.
- In 2007 the FDA rejected a total of 1,368 product shipments from China.
- Food imports from China to the US are big business and getting bigger. In 2006, they represented \$64 billion – a 33 percent increase over 2003.

The "China Problem", Cont.

Chinese-made products have accounted for 60 percent of recalls in 2007, according to the U.S. Consumer Product Safety Commission. In 2007 recalls included bean curd cubes, dried apples, dried peach, dried pear, dried mushrooms, olives, frozen bay scallops, frozen Pacific cod, sardines, dog food, tooth paste, spices.

Can a Chinese Manufacturer be sued?

- From Injured Person's and Importer's perspective:
 1. Can the supplier be subject to personal jurisdiction of the U.S. courts?
 2. Does the supplier have fixed assets in the United States that can be attached to satisfy a U.S. court judgment?
 3. Can the supplier be sued in Chinese Courts?

Where this is headed?

- Unlikely that Injured persons will have rights in the short run directly against a Chinese Supplier, However:
- First, contracts with Chinese exporters will be amended to include specific indemnities in favor of the importer on product safety and quality issues.
 - Second, contracts with Chinese exporters will be amended to include a specific provision requiring the Chinese seller to obtain and maintain sufficient product and general liability insurance, with a reputable U.S. or international insurance carrier, or to have sufficient, attachable, assets in the U.S.

Manufacturer vs Retailer – Lines Blur

- **Manufacturer** – A “manufacturer” is defined as a “product seller who designs, produces, makes, fabricates, constructs, or remanufactures the relevant product or component part of a product before its sale to a user or consumer....”
- **Retailer** – “The reason for excluding non-manufacturing retailers from strict liability is to distinguish between those who have actual control over the product and those who act as mere conduits in the chain of distribution.”

Manufacturer vs Retailer – Strict Liability

- In states that have adopted the Restatement of Torts 2d, any seller in the chain of distribution of a defective product may be held strictly liable for harm caused by the product.
- Even in states that have not adopted the Restatement approach, further manufacturers/retailers may still be held strictly liable if the original manufacturer is bankrupt or can not be served.

Manufacturer – Common Law - Restatement

- Also, in many states, a retailer of a product manufactured by another, which holds itself out to the public as the product’s manufacturer, has the status of a manufacturer and is subject to the same liability damage caused by a defective product.
- **Justification:** Where a defendant puts out a product as its own, the purchaser has no means of ascertaining the identity of the true manufacturer, and it is thus fair to impose liability on the party whose actions effectively conceal the true manufacturer's identity.

What is the "Bottom Line?"

- The entire chain of distribution is impacted

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APPENDIX 1

Ensuring Safety and Quality of Products Manufactured in China

By
Scott Rickman

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Action Plan for Importer Safety - Evaluate

Adopt a Risk-Based Supplier Approval Process:

- Supplier Questionnaire
- Company/3rd Party Audit (based on assessment)
- Supplier evaluation (to include facility and process security)

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Action Plan for Importer Safety - Evaluate

Consideration Factors:

- Ingredient/Packaging Type
- Country of Origin
- Volume
- History
- Exposure/Impact to Business Unit(s)

Focus Levels:

- High = 1
- Medium = 2
- Low = 3

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Action Plan for Importer Safety - Evaluate Ingredients:

An ingredient will be evaluated and scored based upon its (1) potential for adulteration/contamination, (2) functionality, and (3) cosmetic attributes

Country of Origin:
 Evaluated based on the country's ability to demonstrate compliance with U.S. food safety standards and U.S. facility/process security standards

- 1 = Does not typically conform to U.S. standards
- 2 = Has similar standards but differences in interpretation or enforcement
- 3 = Standards are equivalent to U.S. standards Ingredient/Packaging Type

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Action Plan for Importer Safety - Evaluate

- Volume: Evaluated based on the dollar value of annual purchases by the Company
 - 1 > \$5 million
 - 2 = \$2 - \$5 million
 - 3 < \$2 million
- History:
 - 1 = No history or negative history
 - 2 = New facility or supplier with previous minor compliance issue
 - 3 = Current supplier in good standing
- Exposure/Impact to Business Unit: Evaluated based on impact an issue could have to the BU or Company:
 - 1 = Impacts the entire company
 - 2 = Impacts a business unit
 - 3 = Impacts a product

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Action Plan for Importer Safety - Evaluate

Once a Cumulative Score is determined, Potential Supplier will be classified into 1 of 3 categories:

Group A (higher risk) - Score of 5 to 10

- ◆ Must have on-site assessment at approval
- ◆ Certificate of Analysis must accompany all shipments
- ◆ 100% Inspection upon Arrival of incoming product

Group B (medium risk) Score of 11 to 14

- ◆ May require on-site assessment at approval
- ◆ High Inspection Rate of incoming product

Group C (low risk) Score of 15

- ◆ On-site assessment normally not required at approval
- ◆ Regular Inspection of incoming product

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Action Plan for Importer Safety - Verify

Verify compliance of foreign producers with Company safety and security standards

- Audit existing suppliers (scheduled and unscheduled)
- Feet on the ground

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Action Plan for Importer Safety - Test

- Product Sampling and Testing
- Adopt a risk-based approach
 - Some or All?
 - Test Where?
 - Test When?
- Test the "Testers"
 - Training
 - Calibration of Equipment
 - Documentation & Communication

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Action Plan for Importer Safety – Be Prepared for the Worst

- Identification and Traceability
- Ingredients and Packaging must be traceable back to its source
- Finished Product must be traceable through distribution chain
 - Lot Number
 - Production Date
 - DC/Customer
 - Updated Systems
 - Speed is critical
- Bioterrorism Rules

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Import Compliance Procedures and Best Practices

All importers should have the following:

- Internal audit (pre and post-entry) procedures
 - Review paperwork generated by all entities in supply chain (seller, exporter, carrier, freight forwarder, and customs broker)
 - Conduct periodic review of import transactions, including review of complete audit trail – purchase order to payment (“womb to tomb”)
 - Implement corrective action for any systematic deficiencies
 - Make prior disclosure, if necessary
- Annual training (general awareness and specific issue training)

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APPENDIX 2

Sample Contract Language

Ensuring Safety and Quality of Products Manufactured in China By Scott Rickman

Inspections. Representatives of Acme may enter and inspect the production of the Products, the Factory and any warehouse at which the Products are stored, during the time of production, storage, or clean-up periods. The inspection may include all aspects of PROCESSOR's quality control, sanitation procedures, seamer performance "tear down" documentation and records, but only as such pertain to the Products. PROCESSOR may restrict access by Acme's representatives to only those areas where the Products and ingredients and materials for the Products are processed, tested, or stored. PROCESSOR shall maintain and make available to Acme upon request all records of chemical, physical, microbiological, and process tests of the basic ingredients and packaging materials, intermediate products, and finished Products that PROCESSOR conducts or that it requires from its suppliers. Any such inspection or testing by Acme shall be gratuitous and shall not (i) relieve PROCESSOR of its obligations under this Agreement or (ii) constitute acceptance by Acme of any portion of the Products. Acme shall receive the Products subject, at Acme's discretion, to inspection and approval of the lot or lots, or submitted samples from the lots, by Acme's quality control personnel within a reasonable time after receipt. Payments by Acme for any quantity of the Products shall not constitute approval or acceptance of such Products. If any quantity of the Products is defective or does not conform to samples, descriptions, or the Specifications, Acme may, at its option, reject or revoke acceptance of all of such quantity, accept all of such quantity, or accept any commercial unit or units of such quantity and reject the rest. PROCESSOR shall assume all costs of transportation and handling both ways for such rejected Products. PROCESSOR shall remove Acme's trademarks, trade name, and any other marks identifying Acme or Acme's from any rejected Products and the case artwork before PROCESSOR disposes of such Products. Upon request of Acme, PROCESSOR shall certify in writing to Acme that all such trademarks, trade names, and identifying marks have been removed from any rejected Products. PROCESSOR shall furnish to Acme samples of the Products that Acme reasonably requests for quality control testing and evaluation. Samples for recut at Acme facility will be considered as part of the overall production yield. If the production during any one calendar day for the Products is one hour or more, PROCESSOR shall separately code each case of the Products to be readily identifiable by two hour intervals based on PROCESSOR standard operating procedure. In addition to ongoing inspections by Acme employees, there is a requirement for annual Third Party Audits. Third Party Auditors are defined as recognized industry auditors (e.g. AIB, FPASafe, etc.). Acme will schedule the Third Party Audits and notify PROCESSOR no less than 30 days prior to the date of the inspection. If the facility receives an unsatisfactory score as defined by the Third Party Auditor, a follow-up audit will be scheduled 6-9 months from the date of the inspection.

Insurance. PROCESSOR shall maintain in full force and effect during the term of this Agreement comprehensive general liability insurance coverage, including contractual liability and products/completed operations liability coverage, with an insurer approved by Acme and with Acme named as an additional insured, with minimum limits of \$10,000,000 combined single limit for bodily injury and property damage per occurrence, with a responsible insurance carrier acceptable to Acme. Such insurance shall be on an occurrence or claims made basis; that is, it shall cover any claim made for injuries or damages arising out of an event occurring during the term of the policy regardless of whether the claim is made after the expiration of the term of policy. PROCESSOR shall maintain in full force

and effect during the term of this Agreement product recall insurance, with an insurer approved by Acme and with Acme named as an additional insured, with minimum limits of \$5,000,000. Before commencement of any production under this Agreement, PROCESSOR shall furnish Acme with certificates of insurance evidencing the above coverages. Such certificates shall contain a clause for notification of Acme ten (10) days in advance of any cancellation, reduction, or change in coverage.

QUALITY ASSURANCE

- (a) Processor shall, at Processor's expense, draw two (2) cans per shift representing each Product produced and forward Product samples by air freight on a weekly basis to Acme's Research Center. Additional samples requested shall be at Acme's expense. Processor shall draw such samples according to a sample plan set forth in the Specifications. Acme and Processor shall work together in the timely accumulation and approval or rejection of each lot sampled. Acme may reject Product that fails in any respect to meet the Specifications. Acme shall use reasonable efforts to inspect samples prior to shipment of the lot(s) of Products from which the samples were drawn.
- (b) Processor shall timely prepare and submit to Acme such quality control records as may be reasonably requested by Acme from time to time. Acme may also have access to, with reasonable prior notice, Processor's process and quality control records for the Product lots submitted to Acme in order to confirm compliance with the Specifications.
- (c) Acme shall notify Processor of Products containing non-conformities with the Specifications sufficiently minor that such Products are not rejected by Acme. Such notice may be accomplished by providing Processor with copies of quality control records generated by Acme relating to the Products.
- (d) Nothing in these provisions or processes (including, but not limited to, the acceptance of samples or Products containing non-conformities with the Specifications) shall be deemed to constitute a waiver of any of Acme's rights to reject Product for defects not reasonably detectable during inspection of samples as provided above.
- (e) Processor's facility, at which Products are produced, shall be audited on an annual basis by an independent auditor in accordance with the National Food Processor Association's Supplier Audits for Food Excellence ("NFPA-SAFE") program or another such audit that is mutually agreed to by both parties. Such audits shall be at Acme's expense, and shall result in a written report.
- (f) At any time during the term of this Agreement, Acme shall have the right, upon reasonable notice, to send one or more of its authorized employees and/or representatives to observe and inspect, during Processor's regular business hours, manufacturing, warehousing and other facilities used to produce, package, store and ship Product or used to store Product supplies. Acme's representatives shall have the right to take for further inspection a reasonable number of samples of Product and Product supplies during such inspection. Acme acknowledges that production of the Products is located within the Processor's facility and that Acme's right to observe

and inspect, as set forth above, shall be limited to those portions of the facility used to produce, package, store and ship Product or used to store Product supplies. Acme's authorized employees and/or representatives shall execute appropriate confidentiality agreements prior to observing and inspecting the manufacturing facility.

- (g) If any portion of Processor's facilities or any of Processor's processes, inventories or equipment are in an unsanitary condition or do not otherwise comply with the Specifications, all applicable laws and regulations related to food products, food production facilities or worker health and safety, or with the other terms and conditions of this Agreement, Processor shall promptly take such action as will correct the deficiencies and bring such processes, inventories and/or equipment into compliance with the Specifications, applicable laws and regulations, and with the terms and conditions of this Agreement.
- (h) Acme, in addition to all other rights and remedies available to it under applicable law, shall have the right before shipment of Product, to reject any Product which has not been produced, packaged, stored or handled in compliance with the Specifications or which is otherwise not in compliance with the terms and conditions of this Agreement ("Nonconforming Product"). Specifically, but not by way of limitation, the parties agree that:
 - i) Acme may reject and refuse to pay for Product which has been produced and packaged during a particular production run if samples from that production run do not conform to the Specifications or are otherwise not in compliance with the terms and conditions of this Agreement; Acme will promptly inform Processor of all samples or Products that do not meet the Specifications regardless of whether or not the samples or Products are rejected.
 - ii) Acme may reject and refuse to pay for any Product which (i) has been damaged during storage or handling by Processor or Processor's agents or consignees; (ii) does not comply with the Specifications; (iii) does not comply with all of the other terms and conditions of this Agreement; or (iv) is otherwise not in good order for sale in the ordinary course of business as a result of actions by Processor. Acme shall have the right to withdraw or recall any Product which Acme has reason to believe does not comply with the Specifications, regardless of whether the Product may be harmful to the public. Acme shall be responsible initially for all costs and expenses incident to such withdrawal or recall, subject to reimbursement by Processor pursuant to Section 10 hereof. Upon notice from Acme of a withdrawal or recall, Processor shall immediately suspend production of Products which are the subject of a withdrawal or recall until further notice from Acme.
 - iii) Any Product supplies, work in process or Product rejected by Acme and reasonably determined by Acme not to be fit for human consumption shall be disposed of by Processor at Processor's cost and expense in a manner which shall absolutely preclude commercial resale for human consumption.

If Acme and Processor mutually determine that such Products, work in process or Product supplies are reconditionable or salvageable, Processor shall dispose of the same as mutually agreed in writing between Acme and Processor, with the understanding that Processor will sell outside normal commercial channels so as to maximize salvage value.

- (i) If Acme has paid Processor for any Product which is rejected by Acme as permitted under this Agreement, Acme may invoice Processor for the cost of such rejected Product and for any Product supplies therefor supplied by Acme hereunder and also for any freight, handling and other reasonable disposition costs or expenses incurred by Acme in connection with such rejected Product, and Processor shall, at Acme's election, either pay Acme or give Acme a credit in the sum of such invoice amount within thirty (30) days of such invoice. In the event Processor has produced or shipped Nonconforming Product, Acme may, at any time thereafter, order Processor to suspend the production and packaging of Product until such time as Processor has corrected the conditions that resulted in the nonconformity.
- (j) Processor shall make available, at Acme's request, the results (including all documentation and reports generated either by Processor or a government agency) of all inspections and sanitation audits, and inspections and audits conducted by Processor, conducted during the period from sixty (60) days before to sixty (60) days after the term of this Agreement and relating to or affecting Processor's facilities, or any equipment, raw materials, ingredients, packaging materials, work in process or Product located therein. Processor shall provide such documentation and reports within three (3) days of Acme's request therefor. Processor shall notify Acme's designated quality assurance representative immediately by telephone of the occurrence and results of any such inspections or audits.
- (k) Processor shall notify Acme's designated quality assurance representative by telephone within 48 hours of the presence of any Product which fails to conform to the Specifications, and shall comply with Acme's directions regarding the disposition of same.
- (l) Processor shall immediately notify Acme by telephone and by facsimile of any situation which could result in the seizure, destruction, recall or withdrawal of any Product or of the need for any seizure, destruction, recall or withdrawal of any Product. Processor shall cooperate fully with Acme in implementing any seizure, destruction, recall or withdrawal of any Product, including without limitation, assisting Acme in determining the scope and cause of any Product problem and the location of any shipments of Product.
- (m) Unless the nonconformity or defect in any Product subject to seizure, recall, withdrawal or destruction is not attributable to any act or omission on the part of Processor, Processor shall reimburse Acme upon demand for all reasonable losses, damages, costs and expenses incurred by Acme in connection with its seizure, destruction, recall or withdrawal of such Nonconforming Product, all amounts paid by Acme for any Product so seized, destroyed, recalled or withdrawn, and Acme's cost of Product supplies (if any) furnished by Acme to Processor and incorporated into such seized, destroyed, recalled or withdrawn Product.

RECORDS AND AUDIT:

Processor agrees to make and keep full and accurate books and records currently updated with respect to production runs, inventories and shipments, and agrees to report such data as reasonably requested by Acme. Upon twenty-four (24) hours' prior notice to Processor, Acme or its agents shall be permitted to inspect such books and records and make copies thereof.

INDEMNIFICATION AND LIABILITY INSURANCE:

- (a) Acme agrees to indemnify Processor against any claim, loss, damage, liability or expense (including attorneys' fees) for bodily injury, death or property damage where such injury, death or damage is caused by any ingredients, materials, or instructions furnished by Acme to Processor, by any negligence of Acme or by any act or omission on the part of Acme in violation of this Agreement. Acme further agrees to indemnify Processor against any claim, loss, damage, liability or expense arising out of labeling provided by Acme or product claims made by Acme except to the extent such claim or liability arises out of acts or omissions of Processor.
- (b) Processor agrees to indemnify Acme against any claim, loss, damage, liability or expense (including attorneys' fees) for bodily injury, death or property damage where such injury, death or damage is caused by any ingredients or materials furnished by Processor, by any negligence of Processor, or by any act or omission on the part of Processor in violation of this Agreement. In the event of a recall or any seizure of any Products produced hereunder, and in the event such recall or seizure has resulted from any act or omission of Processor, Processor shall reimburse Acme for all damages and expenses incurred by Acme in connection with the recall or seizure, and shall replace the Products subject to the recall or seizure.
- (c) The foregoing indemnification obligations are conditioned upon the party claiming indemnification promptly furnishing the other party with written notice of each claim, loss, damage or expense for which indemnity is claimed and permitting the indemnifying party to assume the defense thereof at its sole cost and expense.
- (d) Acme and Processor shall each maintain insurance to cover the liabilities with respect to which the indemnities are provided for in this section. Such coverage shall be of no less than \$5,000,000 for bodily injury, including death, and property damage combined. Each party shall name the other as an additional insured under such policy and shall furnish to the other upon request evidence of such insurance in the form of a certificate or certificates issued by its respective insurance carrier, which certificate shall provide that there shall be no material change in, or cancellation of, such insurance unless thirty (30) days' prior written notice of such change or cancellation is given to both parties.

LABOR, EMPLOYMENT, ENVIRONMENTAL AND CUSTOMS MATTERS: Processor shall not engage in any unfair labor, wage or benefits practice or practices in violation of the laws of the country of manufacture of the Products or involving unsanitary, unhealthy, and/or unsafe labor conditions, the employment of child, forced, indentured, involuntary, prison or uncompensated labor, the use of corporal punishment, discrimination based on race, gender, national origin or religious beliefs, or similar employment activities and conditions. Processor shall comply with all

applicable laws, rules and regulations including, but not limited to, those pertaining to environmental practices or procedures, in the performance of Processor's obligations under this Agreement. Processor shall comply with all applicable laws, rules and regulations governing the provision of services or the international sale of goods. Processor shall not engage in any activity which is in violation of U.S. customs laws or regulations, international agreements, the laws of the country of manufacture of the Products governing international sale of goods. For purposes of this provision, "child labor" means the use of children who are less than fifteen (15) years of age.

ACC Extras

Supplemental resources available on www.acc.com

Product Sourcing Distribution in China.

Program Material. February 2007

<http://www.acc.com/legalresources/resource.cfm?show=20077>

China Trends: 2008 Perspective.

Quick Reference. November 2008

<http://www.acc.com/legalresources/resource.cfm?show=158217>

An Insider's View of Doing Business in China.

Article. October 2008

<http://www.acc.com/vl/membersonly/Article/loader.cfm?csModule=security/getfile&pageid=275194&page=/legalresources/resource.cfm&qstring=show=275194&title=An%20Insider%26%2339%3Bs%20View%20of%20Doing%20Business%20in%20China>

Please note, these additional resources are provided by the Association of Corporate Counsel and not by the faculty of this session.