



IMPORT & EXPORT

BORDER GATEWAY SUMMIT IV

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The “Inter-Mestic Relationship”

- Provides New Markets – International
 - Complimentary vs. Competitive
- AND***
- Geographic Proximity
 - Business friendly climates in Canada & US; particularly Canada
 - Well-established rules of the game

Canada is Not the 51st State

WELCOME!

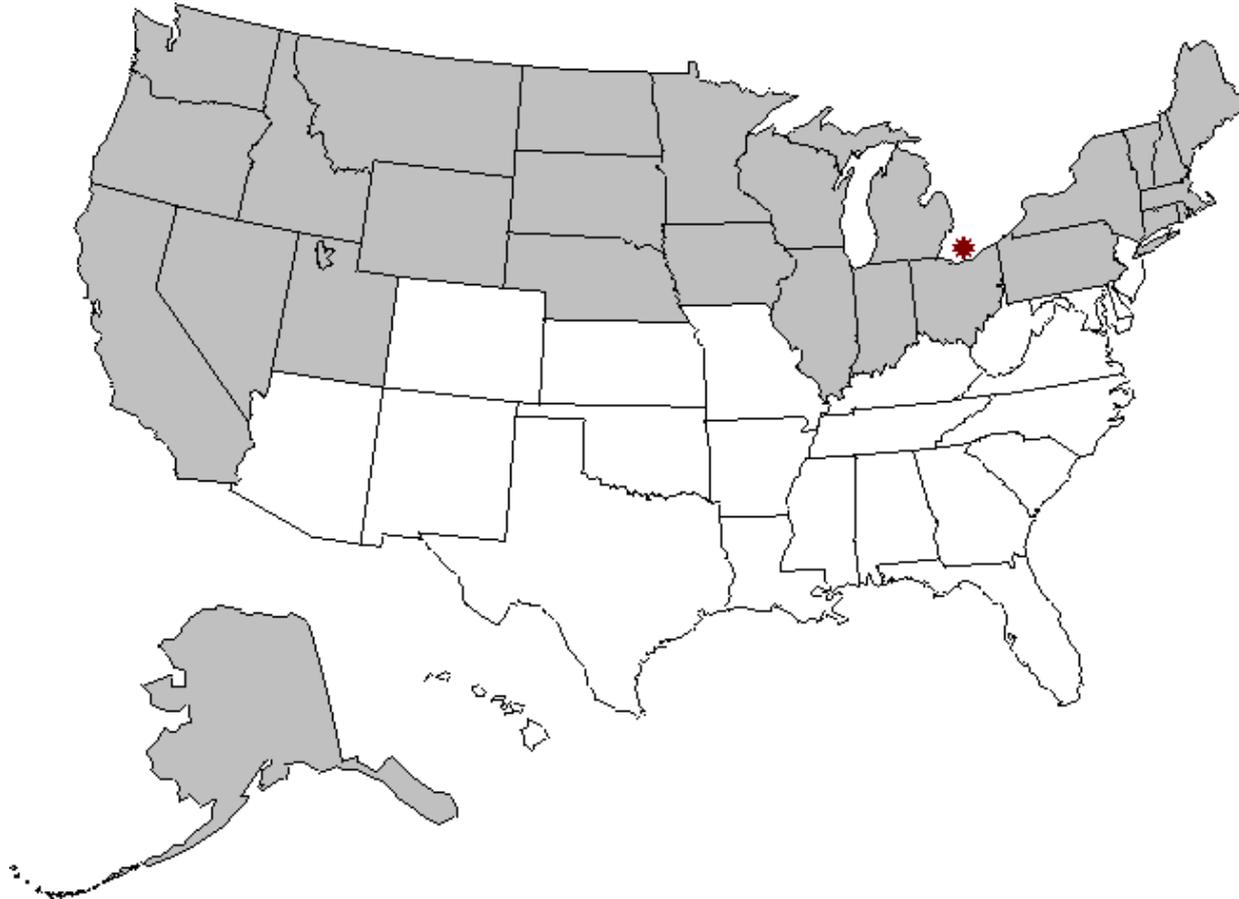
This play structure is designed for
2-5 Year olds - United States
1.5 - 5 Year olds - Canada

Although this equipment meets requirements of ASTM F1487 - 98 for ages 2 - 5 and CAN/CSA - Z614 for ages 1.5 - 5, some equipment may not be appropriate for all children in this age group.

- Attentive Adult supervision is strongly recommended for children using this equipment.
- Loose clothing, clothing with draw strings and items worn around the neck must be avoided to prevent string entanglement.
- Debris, especially sharp items, ropes and cords must be removed from play area immediately.
- Extra care must be taken when conditions are damp, snowy, icy or hot.
- Regular inspection of play equipment is vital. Report missing, worn or damaged parts to the owner.
- Care must be taken near swings and other moving equipment to avoid injury.

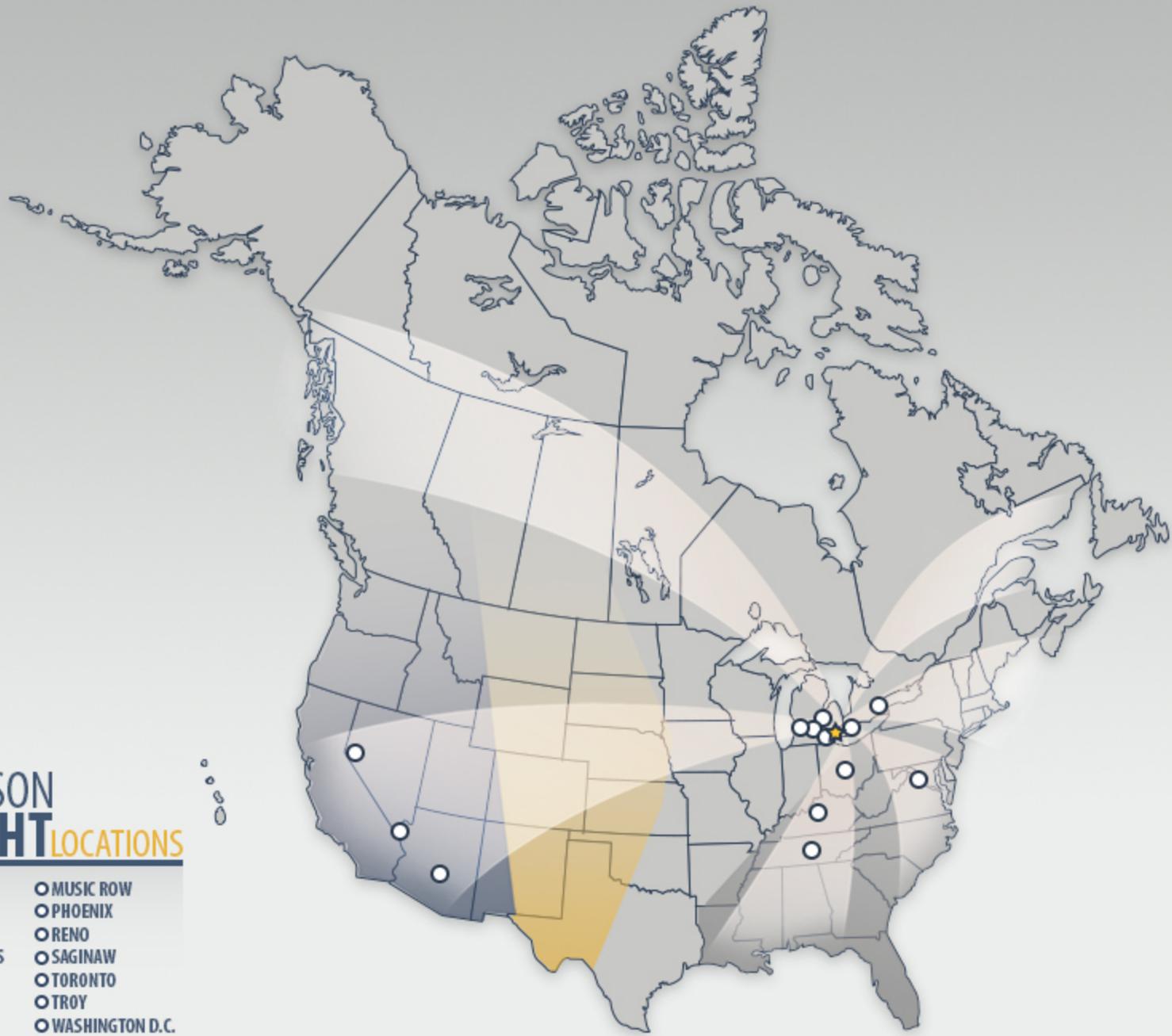
IMPORTANT: The U.S. Consumer Product Safety Commission (CPSC) and the Canadian Standards Association (CSA) state that the safety requirements for playground equipment are not the same for the United States and Canada.

But Are These States in Canada?



A Few Words About NAFTA

- The North American Free Trade Agreement is a regional trade agreement between Canada, the US, and Mexico.
- “Free Trade” in Goods and Services between the Member Countries through the reduction of tariffs and elimination of NTBs
- Facilitates Direct and Indirect Investment into the countries
- Protections for fair and non-discriminatory treatment
- Dispute resolution mechanism – private investor v. governments
- **THE NAFTA ESSENTIALLY GUARANTEES THAT YOU WILL BE TREATED JUST LIKE A DOMESTIC COMPANY – FREE TRADE DOES NOT MEAN “TAX FREE” TRADE**



DICKINSON WRIGHT LOCATIONS

- ANN ARBOR
- COLUMBUS
- DETROIT
- GRAND RAPIDS
- LEXINGTON
- LANSING
- LAS VEGAS
- NASHVILLE
- MUSIC ROW
- PHOENIX
- RENO
- SAGINAW
- TORONTO
- TROY
- WASHINGTON D.C.
- WINDSOR



Before the Border



BEFORE

- INTELLECTUAL PROPERTY
- DISTRIBUTION CHANNELS (sales agents, distributors, licensing, franchising)
- EXPORT CONTRACT / POs
- TAXES
- CORPORATE STRUCTURING

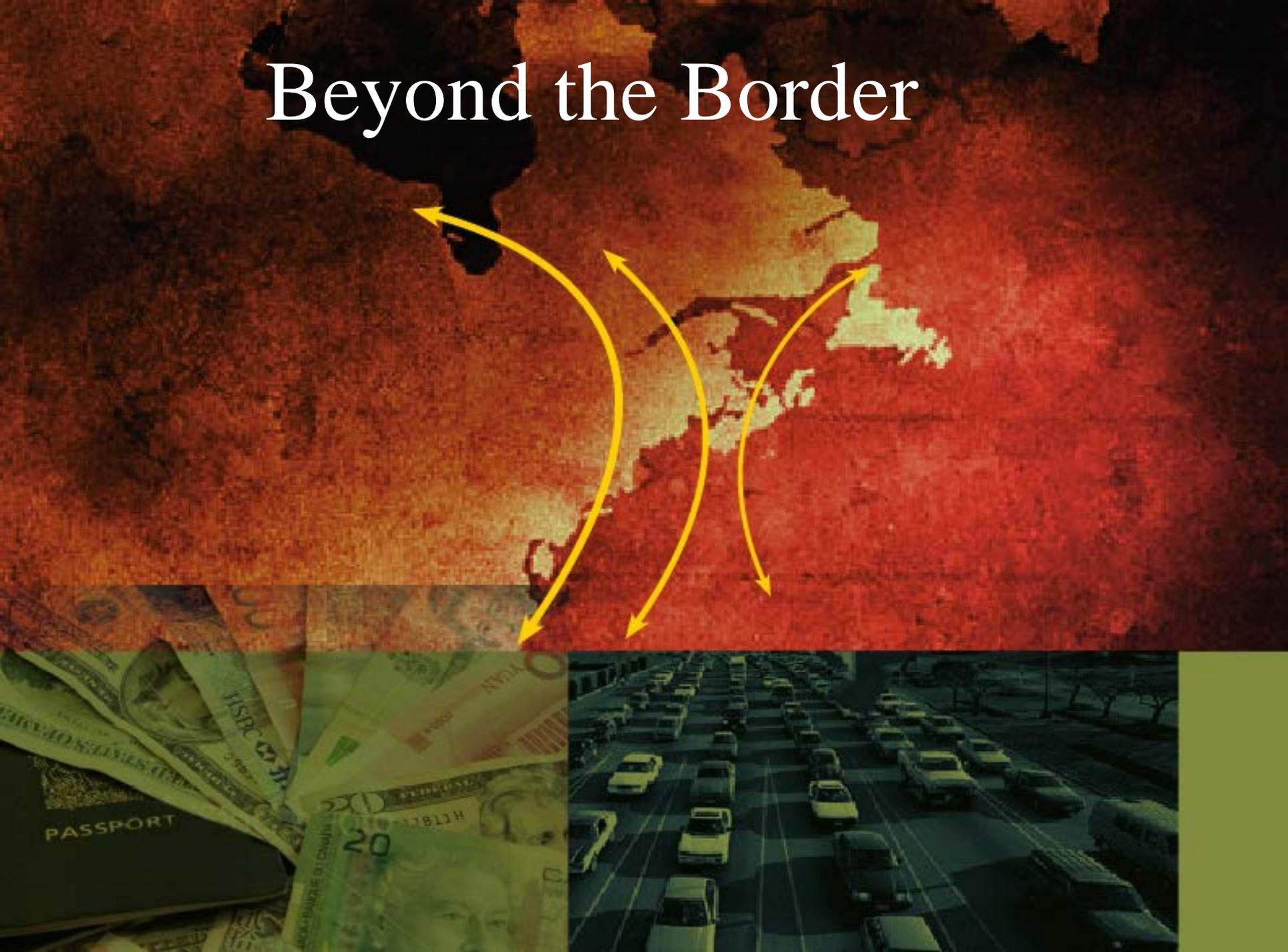
AT THE BORDER



at

- CUSTOMS
- COUNTRY OF ORIGIN vs. MARKING
- EXPORT CONTROLS e.g., CUBA, IRAN
- BUSINESS IMMIGRATION

Beyond the Border



BEYOND

- MARKING vs. LABELLING
- EMPLOYMENT STANDARDS
- REGULATORY STANDARDS

BUT

- BEYOND THE BORDER
- REGULATORY COOPERATION
COUNCIL

WHY COMPLIANCE MATTERS

Timelines for Final Rules

- Preventative Controls - Human Sept. 17, 2015
- Preventative Controls - Animal Sept. 17, 2015
- Produce Safety – Oct. 31, 2015 (to Fed. Reg.)
- FSVP – Oct. 31, 2015 (to Fed. Reg.)
- Accreditation of 3rd Party – Oct. 31, 2015 (to Fed. Reg.)
- Sanitary Transportation – Mar. 31, 2016 (prop)
- Food Defense – March 31, 2016 (prop)

Yates Memo

Sally Quillian Yates, Deputy Attorney General

September 9, 2015

To assistant attorney generals

Subject: Individual Accountability for Corporate Wrongdoing

“One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.”

“...make it all the more important that the Department fully leverage its resources to identify culpable individuals at all levels in corporate cases.”

“Thus, civil attorneys investigating corporate wrongdoing should maintain a focus on the responsible individuals, recognizing that holding them to account is an important part of protecting the public fisc in the long term.”

“In order for a company to receive any consideration for cooperation under the Principles of Federal Prosecution of Business Organizations, the company must completely disclose to the Department all relevant facts about individual misconduct.”

“Both criminal and civil attorneys should focus on individual wrongdoing from the very beginning of any investigation of corporate misconduct.”

Criminal Implications

- Peanut Corporation of America
- Jensen Farms
- Blue Bell (in operation for 108 years)
- Chipotle
- Imported Cucumbers



FSMA REPORTING and RECORDKEEPING

Dan Ujcz

New FDA Authorities

- Increased Inspections
- Increased Records Access
- Mandatory Recall Authority
- Import Certification Authority
- Fees for Reinspection
- Administrative Detention
- Facility Registration and Suspension of Regis.



Records and Record Access

- Expanded Record Access – 24 hours
 1. Food Safety Plan
 2. FSVP
 3. Food Defense Plan
 4. Sanitary Transportation
 5. FDA Access during emergency
- ELECTRONIC (preference)



Corporate Liability

- New Prohibited Acts
 - Failure to Comply – Csuite on the hook
- Facility Registration
- Records Retention and Access
- Importer of Record
- Fees / Monetary Penalties
- INTENT IS NOT REQUIRED

FOOD SAFETY PLAN

Preventive Controls for Human Food

Compliance Dates after publication of final rule:

- **very small businesses:** <\$1 million per year in sales of human food plus the market value of human food manufactured, processed, packed, or held w/o sale), 3 years, except records to support its status in January 2016
- **small business:** <500 FTE, 2 years
- **All others:** one year

General:

- Individual(s) with food safety training/experience to design and implement plans
- Plan must be onsite and be made available to FDA upon request
- Recommendation: create a Food Safety Team

FSMA SUPPLY CHAIN ISSUES

Dan Ujcz

FSMA's Subpart G

- The Receiving Facility must implement a risk-based written supply-chain program for raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain applied control.
- Importers under FSVP do not have to implement.
- Not for food for research or evaluation.

General Requirements

- Use only approved raw materials and other ingredients and Written Procedures to ensure
- Determine appropriate Supplier Verification Activities (SVAs)
- Conduct SVAs
- Document SVAs
- Assure that a hazard requiring a supply chain control has been significantly minimized or prevented

SVA Considerations

- Nature of the raw material or ingredient hazard
- Entity approving the control
- Supplier's Procedures for hazard control
- Supplier's regulatory compliance history and status
- Supplier's Food Safety history

SVA

- Onsite Audits
- Sampling and Testing
- Review of Suppliers Food Safety Records, including consumer/customer complaints
- Other procedures based on supplier performance and risks associated with the product
- Must be done before using the raw materials or ingredient.

Results of SVA

If supplier not controlling hazards the receiving facility must take prompt action to ensure that the raw materials or other ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated.

Who Approves the Supplier

- Receiving Facility
- Other entity BUT the receiving facility must still review and assess those activities AND document
- Supplier may conduct sampling and testing BUT subject to review by receiving facility BUT cannot accept additional verification by supplier
- Third Party Audits

Conducting SVAs

- One or more of the four PRIOR TO USE of raw materials or ingredients
- Hazard controlled by the supplier (SAHCODHA) and on-site audit by supplier is required and at least annually thereafter unless other verification activities
- Qualified facilities OK – but of course provide written assurance in compliance with FDA

SVA RECORDS

- Written Supply Chain Program
- Approval Documentation to Supplier
- Written Procedures for Receiving Raw Materials and other Ingredients
- Documentation Demonstrating Use of Written Materials
- Documentation of the Determination of SVAs
- Documentation of the On-Site Audit

SVA RECORDS

- Documentation of Sampling or Testing
- Documentation of Review of Supplier's Relevant Food Safety History
- Documentation of other SVAs
- SAHCODHOA – EVERYTHING
- Qualified Facility Status of Supplier or Inspection Results
- Non-Conformance Actions
- Third-Party Reviews

FSMA FSV and INTERNATIONAL

Dan Ujcz

FSMA's International Tool Kit

- Foreign Supplier Verification Programs (301)
- Voluntary Qualified Importer Program (302)
- Mandatory Certification (303)
- Prior Notice (304)
- Building Capacity of Foreign Govs. (305)
- Improved Enforcement Authorities (306)
- Accreditation of 3rd Party Auditors (307)
- Foreign Offices (308)

(a) Foreign Supplier Verification Program (FSVP)

Overview of FSVP

- Importers are required to develop, maintain, and follow a FSVP for each food imported unless an exemption applies
- The requirements vary based on:
 - Type of food product
 - Category of importer (e.g., small)
 - Nature of the hazard
 - Who/what is to control the hazard

Exemptions

- Importation of juice and seafood whose suppliers are in compliance with HACCP regs.
- Food imported for research or evaluation purposes
- Food imported for personal consumption
- Alcoholic beverages
- Food that is transshipped or that is imported for future export (not US consumed or distributed)
- Low acid canned food req. (microbiological haz only)

The “Significant Seven”

1. Compliance Status Review of Foods and Suppliers
2. Hazard Analysis
3. Supplier Verification Activities
4. Corrective Actions
5. Periodic Reassessment
6. Importer Identification at Entry
7. Recordkeeping



Importer or Importer's Customer Controls Hazard

- Usually raw product
- Document hazard and sign your name on dotted line
- Conduct Investigation & Corrective Actions
- Reassess FSVP
- Ensure Importer Identification at Entry
- Maintain Records

Hazards Controlled by Foreign Suppliers

- serious adverse health consequences or death to humans or animals (SAHCODHA)
- Initial onsite audit then at least annually



Microbiological Hazards in Produce

- Conduct Initial Audit and then at least annually



Other Hazards

- Onsite Auditing
- Sampling and Testing
- Review of Foreign Supplier and Food Safety Records
 - Compliance history
 - Adverse events / Recalls
- Other Measures

Special Procedures

- Dietary Supplements
- Small Importers <USD 1,000,000
- Officially Recognized of Equivalent Food Safety Systems (New Zealand)



FSMA ISSUES

- Definition of Importer
- Port Shopping (Prior Notice)
- Record Keeping (Electronic)
- Compliance History (Open Kimono?)
- Third-Party Auditors

Food Products into Canada

What If ?

- Once CFIA is alerted to potentially unsafe food it immediately posts online warnings and distributes them via traditional media and social media
- Outbreak Central (a web-based application) shares results of outbreak investigations
- Public Health Agency of Canada is in regular contact and shares information with the U.S. Centers for Disease Control and Prevention

Importing into Canada

- Ensure that products meet ALL requirements of Canadian legislation (federal, provincial and municipal).
- Register your Business
- Follow Good Importing Practices
- Maintain Books and Records in Canada
- Get Licensed

Deep Thoughts by Dan Ujcz

- “Educate before We Regulate”
- The goal is food safety, not enforcement cases
- Past Experiences with Trusted Industry Programs / Voluntary?
- Budget?
- Bureaucratic Response
- COOL and Other Trade Action

The “Clear”

- Canada-US Regulatory Cooperation Council



OTHER CAN-US ISSUES

- Intellectual Property
- Business Immigration
- Canada Anti-Spam Legislation



EXPORTS AND THE NEW CHINA
FOOD SAFETY LAW

China's Food Safety Law (2015)

- Not the first, but it is the strictest in China's history
- Became effective October 1, 2015
- Transformed prior segmented regulations into a relatively unified system
- Increased the scope and extent of punishment for violations

Imported Food in China

- China is a top three food market, along with the US and the EU
- Scandals like melamine laced infant formula cast cloud over domestically produced food
- Chinese consumer preference for safe foreign food
- China now has world's highest annual growth rate for food imports

The New Law and US Exporters

- China's new Food Safety Law (FSL) has an entire chapter dealing with imports and exports
- China's Food and Drug Administration (CFDA) is the primary regulator
- But for US exporters a key regulator will be the the AQSIQ (General Administration of Quality Supervision, Inspection and Quarantine)

Exporter and Producer Filings

- FSL Article 96 requires that overseas exporters and Chinese importers be “put on record” with the AQSIQ
- Overseas food producers of meat, aquatic products, dairy products and bird’s nest exported to China must complete a more rigorous registration process
- AQSIQ publishes lists of overseas exporters and producers and Chinese importers

Import Process

- In the new FSL, China sought to balance consumer demand for foreign food products with the objective of assuring safe food without over-regulation
- The new FSL reflects a shift from supervision and inspection at ports of entry to source control and on-site inspection of producers in the country of origin
- Procedures at the border to be based on assessment of risk of particular products and compliance records of producers, exporters and importers

Traceability and Recall

- The new FSL establishes full supply chain traceability for food safety, together with a food recall system
- AQSIQ has launched an upgraded electronic filing system to capture import data and sales records of imported food
- Greater responsibility is placed on food importers to ensure compliance by overseas exporters
- Anticipate expansion of on-site audits and full supply chain traceability (limited to infant formula currently)

Online Food Sales

- Rapid expansion of online food sales from abroad (called “haitao”) had been the “Wild West” of food sales in China
- Online sales are now subject to the same rules as “brick and mortar” sales, including requirements for Chinese language labels and usage instructions that must be posted online
- Online platforms must confirm the true identity of online sellers and monitor their compliance

Final Thoughts

- China's new Food Safety Law remains a work in progress
- Administrative procedures and regulations are in process and will provide further definition
- Efforts to assure compliance with the US FSMA may prove useful to exporters in meeting the requirements of China's new law

**What
should
YOU
DO** ?

- **What should You do?**

- Ignore the problem and hope no one gets sick and you cross your fingers that you can get by without having to admit its existence
- Call your national Association for assistance
- Call the FDA
- Call the State District Agriculture Department agent and advise him of the problem
- Other

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DON'T:**
 - Ignore the problem and hope it goes away
 - Tell all your staff, but rather limit any disclosure to only those in the company who need to know
 - Contact trade associations or anyone beyond your lawyer
 - Speak with any members of the press in case the problem somehow leaks out
 - Retain any expert to take any other action without first going through legal counsel

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DON'T (cont):**

- Immediately contact the FDA or any other federal, state or local governmental regulatory agency
 - Under the Reportable Food Registry (“RFR”), 21 U.S.C. 350f, a report must be made of a food contamination/adulteration problem within 24 hours of determining that the food poses a **reasonable probability** of causing serious adverse health consequences or death to humans or animals

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DON'T (cont):**
 - A common misbelief is that this regulation requires a reporting to the Reportable Food Registry of **becoming knowledgeable of a potential food contamination/adulteration problem**

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DO:**
 - Immediately contact legal counsel knowledgeable of federal, state and local regulations involving food production and adulteration/contamination issues, including recall and market withdrawal
 - Conduct an investigation under the direction of such an attorney, which needs to be done ASAP, but at the same time insure that the investigation is as complete as possible

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DO (cont):**
 - Provide immediate verbal confirmation by written notice of a claim for coverage to all insurers that provided you with any policies that might afford coverage as well as the agents through whom such coverage was procured

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DO (cont):**
 - Through your legal counsel:
 - Retain expert assistance (e.g. specific to contamination issue)

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DO (cont):**
 - Retain a **local crisis management public relations firm** and if you suspect food product has been distributed nationally, a **national crisis management public relations firm** to deal with the press and potential communications with some of the other regulators and third parties (e.g. wholesale customers, such as distributors & retail customers, such as supermarkets)

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DO (cont):**
 - Conduct a re-testing of product by a private lab on an expedited basis
 - Trace the source of contamination

Dos and Don'ts When Faced With a Potential Food Contamination/Adulteration Problem

- **DO (cont):**
 - If results confirm the existence of a harmful contaminate then develop a proposed recommendation for a market withdrawal or recall classification to be presented to federal and state regulators, including specifically the FDA if the product is sold in **inter**state as opposed to **intra**state commerce

A 3D rendering of a white, stylized human figure in a thinking pose, standing next to a large, red, 3D question mark. The figure is positioned to the right of the question mark, with its hand resting on its chin. The question mark is a thick, red, 3D shape. The background is a plain white surface. A horizontal grey bar with white text is overlaid across the middle of the image.

ARE THERE ANY QUESTIONS?