

Recent Developments in US Product Safety

Product Safety in a Global Marketplace Seminar

Munich

Joe Cyr

June 19, 2008

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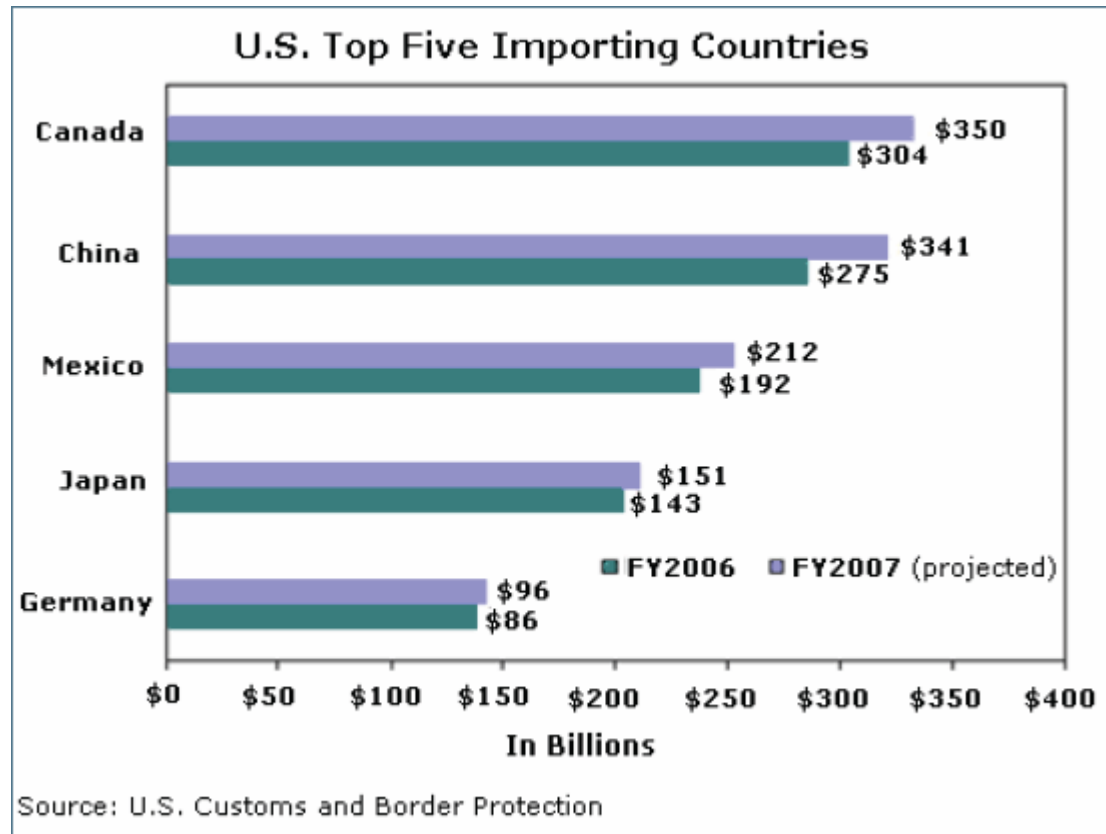
U.S. Government Regulatory Agencies

- US Consumer Product Safety Commission
- US Food and Drug Administration
- Other government agencies



Imported Consumer Products

- 101% increase over the last 10 years
 - 85% of toys
 - 59% of electronics
- 44% of all consumer products
- Over 800,000 importers - 300 ports of entry



2007 – Year of the Recall

- 473 products recalled in 2007
 - 82% were imported products
 - 74% were made in China
- No law requires manufacturers to try to find purchasers of the recalled product
 - CPSC study estimates manufacturers cannot account for 70-90% of recalled infant products
 - Consumer groups want CPSC to require registration cards on all products intended for use by children

New US Plan For Import Safety

- 14 recommendations; 50 actions
- Information network
- Safety Standards
- Compliance verification - certification

New US Plan For Import Safety

- Anti – Counterfeiting Trade Agreement
- “United States: Refused Entry”
- Food Protection Plan

FDA – Key Initiatives

- Food Protection Plan - recommends authorizing FDA
 - to accredit qualified third parties for voluntary food inspections
 - to refuse admission of imported food if inspection access delayed or denied
- China Partnerships
 - plan to establish an FDA office in China
 - allow greater access for FDA inspections and help assure that products shipped to the US meet FDA standards
- Future plans to establish an office in India

FDA – Key Initiatives

- Sentinel Initiative
 - National electronic system for monitoring medical product safety
- FDA Globalization Act of 2008
 - Proposes an annual registration fee of \$2000
 - Requires labeling to identify country-of origin
 - Provides FDA with mandatory recall authority
 - Requires mandatory inspection of domestic and foreign drug and device facilities every two years
 - Requires destruction of adulterated, misbranded or counterfeit drugs that a company attempted to import into the country

Consumer Product Safety Commission

- 15,000 products
- 27,000 fatalities and 33.1 million injuries per year
- Deaths, injuries and property damage from consumer product incidents cost the US over \$700 billion per year

CPSC – Recent Developments

- Import Surveillance Division to increase inspections at US ports
- Proposed legislation
 - Child Product Safety Notification Act
 - Infant and Toddler Durable Product Safety Act
 - Consumer Product Safety Reform Act of 2008

Consumer Product Safety Reform Act of 2008

- Increase CPSC funding
- Renovate development and testing facility
- Create public database of deaths and injuries
- Mandate independent third-party testing of children's products

Consumer Product Safety Reform Act of 2008

- Make current voluntary standards mandatory
- Ban paint and children's products that contain more than a minimal level of lead
- Expand the definition of children's products to include all goods that are primarily intended for youths under age 7

What will be the “products” of the future?



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What will be the “products” of the future?

- The challenge of imagining things that aren't!
- Predicting demand as well as technology

Potential Product Safety Issues

- Electromagnetic radiation emitters
- Nanotechnology
- Genetically modified foods

How can multinationals minimize their exposure to product liability?

- Compliance
 - What are the applicable standards?
 - How is compliance measured?
- Quality control – product stewardship throughout life cycle

We need predictability!

- Doctrine of US Federal Preemption
- *Obtaining International Standards*

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