“It’s a complicated world out there”

Many external inputs regulating and influencing our industry:

- EPA
  - Clean Air Act
- FDA
- Local state legislation on Packaging
- EEC: Environment DG
  - Packaging & Waste Directive
    - Recovery, Re-Use and Source reduction
  - ROHS – Manufacture of electrical equipment
  - WEEE – Recycling of electrical equipment
- EEC Food Safety Directive
- French Positive List
- UK Government reviews MAP
- CONEG
- Toxics in Packaging Clearing House (TPCH)

Includes heavy metals in packaging
“It’s a complicated world out there” 2

- Many external inputs regulating and influencing our industry:
  - EEC / Asia: Planning to prevent Packaging
  - EEC / Canada / Japan – Packaging Fees
  - EEC – Plastics Directive
  - Canada – Chemical Management Program
  - EEC – Reach legislation
  - US / Canada / Mexico – Commission on Environmental Cooperation: Sound Management of Chemicals
  - End User Initiatives e.g. IKEA
  - Sensational news stories e.g. “Are plastics safe?” LA Times September 10, 2007 : concerns phthalates + Bisphenol A
You don’t know what you don’t know

- What do we need to know?
  - Legislation that will effect our industry in 1-2 years
  - Future legislation that may be a potential problem
    - Still time to lobby and influence lawmakers
  - Other global trends that may appear in N America
  - Legislation that will / may effect our export business

- Main Topics
  - REACH
  - Migration
  - Food Safety
  - Danger of over reaction
Threat or Opportunity?

- **Threat**
  - Over-legislation make business difficult
  - Potential loss of business
  - Gives overseas competitors advantage
  - Drives business offshore

- **Opportunity**
  - Protect domestic sourcing
  - Turn into competitive advantage
  - Consumer feels more confident with “Packaged in USA”
REACH

Registration, Evaluation, Authorization and Restriction of Chemicals

- New European Chemical Legislation
  - Came into force 1 June 2007. Becomes operational in 2008
  - ‘New’ and ‘Existing’ chemicals treated the same
  - One of the most complex legislations in European Union
  - EINECS and NLP are phase-in substances
  - Reversal of ‘burden of proof’ from authorities to industry
  - Self-enforced; all steps of supply chain are accountable

- All EINECS substances need to be pre-registered
- All EINECS substances need to be registered
- All ELINCS substances fall under REACH on June 1, 2008
Who must to register?

Manufacturers of chemicals must register
Chemical Synthesis A + B → C

Importers of chemicals must register

SunChemical, Køge, Denmark
Who must register?

**EU importer or manufacturer must register**
- Require REACH trained employees or consultants ((eco-)toxicology, risk assessment etc.)
- Estimated time per substance: approx. 30 working days per substance + study monitoring

**Who must register?**
- US SUN Manufacturer
- DIC Manufacturer
- Raw Material Manufacturer
- EU SUN Manufacturer
- Customer
- Are you importer?
- Non-EU Manufacturer

Registration needed
Registration is not needed
REACH - Exemptions

Definitions:

- **Chemical Substance** – A discrete chemical substance typically identified by a CAS or EINECS number; must be registered under REACH

- **Preparation** – A mixture of chemical substances; will require multiple registrations under REACH

- **Article** – EU Article definition is not changed by REACH: "Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition;"

It appears that most packaging will be considered an Article, but suppliers obligation to disclose content information has increased

What is an article do I have one?
The elements of the article definition under REACH are interpreted in the following:

- **The function** of an object is determined by the purpose of its use ("Why is the object used?") For example, the function of a pen is to write and the function of a battery is to provide energy.
- **The shape** of an object is its two- or three-dimensional form (depth, width and height).
- **Surface** means the outmost layer of the object.
- **Design** means the arrangement of the ‘elements of design’ in such a way as to best accomplish a particular purpose. The design of a textile may be determined by the twist of fibers in the yarn, the weave of threads in a fabric and the treatment of the surface of the textile.
- An object is an *article* when the shape, surface and design are more important for the normal use than its chemical composition. The type of user of an article, e.g. private consumers or industrial enterprises, does not have any influence on its status as article.
REACH - Exemptions

I have an “Article”, does this mean I can ignore REACH?

No, if any of the following apply:

- I use substances and preparations made in the EU?
- I import substances and preparations for production of articles in the EU?
- My article contains substances released under normal use conditions.
- My article contains substances of very high concern:
  - Carcinogens
  - Mutagens
  - Reproductive hazards
REACH - Roles

REACH is **not** a Regulatory and Product Safety Initiative!

**R&PS**
- Identify manufactured & purchased Chemical Substances
- Prepare Pre-registration
- Participate in SIEFs and Consortia
- Provide guidance and advice to other disciplines

**IT**
- Assist in data gathering as requested & Provide infrastructure for IUCLID 5

**Purchasing**
- Contact suppliers to determine their intent regarding REACH
- Identify REACH compliant suppliers

**Product Development & Research**
- Prepare Registration Chemical Substances and physical & chemical characterization
- Address gaps caused by suppliers not supporting REACH

**Sales & Marketing**
- Communication with customers regarding supported end-uses
- Communication with customers to identify Chemical substances exported to EU; but not by your company

**Management**
- Sales & Marketing and Manufacturing Strategy
- Handling confidential information; suppliers and customers
- Legal entities and registration strategy
## Cost Estimates

<table>
<thead>
<tr>
<th>Annual Volume (tons)</th>
<th>Time for registration</th>
<th>Estimated cost* (€’000)</th>
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<tr>
<td>&gt;1000</td>
<td>1 June 2010</td>
<td>1.700</td>
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<tr>
<td>&gt;1 and N; R50/53; CMR Cat. 1 and 2</td>
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<td>&gt;100</td>
<td>1 June 2008</td>
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</tr>
<tr>
<td>&gt;1</td>
<td>1 June 2008</td>
<td>25 – 60</td>
</tr>
</tbody>
</table>

*Test cost only excluding cost for employee FTE, consultancy work and authorisation proces. Significant cost reduction through consortia, and read across for similar substances. Registration fees have not been determined.
Migration In The News

Recent News has lead to increased focus on potential for migration from the packaging and from the dangers of imported goods

The key concerns:
- human health
- the environment.

Strictly speaking, the regulations do apply to articles produced by converters, not Adhesives, Pigments, Coatings & Inks.

We will discuss briefly the US regulations as a framework for considering related International Regulations.

Primary US regulations covering these issues are:
- CONEG
- Food Contact
- Toy Contact
Packaging Scare Stories

No risk from photoinitiator found in baby milk*

Background
Recently Nestlé ordered the recall of liquid baby milk in Italy, France, Spain and Portugal, after traces of the photoinitiator ITX a component used in UV packaging-printing-ink, were found to have migrated into the liquid food product.

Position
ITX has a long history of safe use by many food packaging companies. The European Union’s Food Safety Authority (EFSA) upon evaluation of the current situation stated that although considered undesirable, the presence of ITX in food is not likely to present a health risk at the levels reported.

In its technical documentation Ciba implies migration testing by customers of its ITX-product prior to use in specific applications such as food packaging to ensure the safety of the application. These have to ensure, that there is no migration – not even in traces – of the photoinitiator used into the food product to be packaged.

We work closely with our customers to provide knowledge and support and to develop systems to eliminate ITX migration in the future as far as possible or apply alternative technologies.

As a Responsible Care® Company, Ciba is dedicated to the responsible and ethical management of health, safety and environmental aspects of our products throughout their life cycle.

*Ciba Speciality Chemicals Inc. Press Release November 2005
Recent “Scare” Stories

Aug 14 headline: Mattel issues new massive toy recall*
About 9 million items recalled; danger from magnets and lead paint

Counterfeit Colgate Toothpaste Found**
Contains diethylene glycol

Press links to product originating from China

Sources:
*MSNBC Aug 14, 2007
**FDA Press release June 14 2007
Packaging Regulations

CONEG
- Prohibits intentional use of toxics in packaging. Primary concern is heavy metal content, focusing on four metals; combined Cadmium, Lead, Mercury & hexavalent Chromium <100ppm. Suppliers provide Certificates of Compliance.

Packaging and Packaging Waste Directive 94/62/EC
- Goal was “...minimizing the creation of packaging waste material and promotes energy recovery, re-use and recycling of packaging.”
- Includes heavy metal restrictions, currently identical to CONEG

European Community directives ROHS 2002/95/EC & WEEE 2002/96/EC
- ROHS – Manufacture of electrical equipment
- WEEE – Recycling of electrical equipment
- requires the substitution of heavy metals (lead, mercury, cadmium, and hexavalent chromium) and brominated flame retardants (polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE))
- May not be intentionally added, except for levels specified by end-use application
- Strictly speaking applies to the article (waste electrical equipment), not the packaging
- Frequently suppliers to the packaging business are asked for compliance

Variety of Regulations that are complicated and sometimes conflicting
Food Contact

US

Covered under the various Parts of the FDA Regulations under 21 CFR

- Colors – Traditionally the primary focus
  - Color certification and specification including migration criteria
  - Starting materials, additives and by-products
  - Heavy metals

- Other areas for concern:
  - Resins
  - Additives
  - Solvents
  - In-plant Recycling
Food Contact

EU

  - Only applies to human food; in the US FDA regulations cover human and pet food equally
- Resolution AP (89) 1 – outlines analytical test methods and specific limits in colorants for
  - heavy metals
  - Aromatic amines
  - PCB
- French Positive List – Applicable to plastics components
  - Requires reporting of noxious substances offered for sale
  - Requires listing of Dangerous substances above 0.1%
  - Specifies proper labeling and warning requirements
  - Will be augmented in the coming years with implementation of GHS
- Traceability - EC Regulation 1935/2004
  - Came into effect October 27, 2006
  - Requires that systems must be in place to provide positive traceability for material and articles that may come in contact with food
  - Industry groups under CEFIC prepared detailed guidelines for acceptable practices
  - Some companies installed detailed IT infrastructure for tracking and data capture
Toys in the News

US
- Primary US Regulation is CPSC covering lead content, 600 ppm lead is the limit

EU
Primary focus is testing and specification for toys, not raw materials
- Directive 88/378/EEC
  - EN 71-3:1994; Safety of toys — Part 3: Migration of certain elements
  - EN 71-9: 2005; Safety of toys: organic chemical compounds: requirements
  - EN 71-10: 2005; Safety of toys: organic chemical compounds: sample preparation and extraction
  - EN 71-11: 2005; Safety of toys: organic chemical compounds: test methods
TPCH Report

- Toxics in Packaging Clearing House – for US EPA
- June 2007 – Random testing of 355 packages
- 16% exceed 100ppm limit for heavy metals
- 3 reasons
  - Packaging novelties e.g. batteries or circuit boards
  - Packaging is sourced abroad from countries where legislation may not exist or is enforced
  - Complacency among manufacturers and distributors in the packaging supply chain due to lack of enforcement
- Further testing is planned and EPA enforcement of limits expected
Critical Issue Management

- Butyl Benzyl Phthalate (BBP) and Bis-Phenol A (BPA) in food packaging:
  - Articles in local and Trade Press indicate that these plasticizers may be cancer-causing agents because they can leach out of the plastics and migrate into the food.
  - Although FDA regulates these materials and our members might not even use them, the magazine articles cause consumer concerns and without an effective PR and industry involvement it might negatively impact food packaging.

- Recent scare with ITX in aseptic packaging in Europe has further raised consumer concerns regarding packaging – as discussed earlier

- TPCH Report
  - Will lead to an increased level of focus on this issue

- Combined with recent scandals concerning tainted pet food, recalls of toys, counterfeit toothpaste and pharmaceuticals

Major opportunity for FPA membership?
Future Concerns

- **France bans plastics packaging (13/10/2005)**
  
  Oct 12, 2005  Plastics and Rubber Weekly

  Biodegradable bags and packaging will be the only option from 2010. The French Assembly has unanimously voted through legislation banning the sale and distribution of all plastics bags and plastics packaging from 2010, unless they are biodegradable.

  The measure was introduced yesterday by two members of parliament as an amendment during a debate concerning agricultural legislation, according to Michel Loubry, regional director of Plastics Europe in France. The French environment ministry was unaware of the legislation, said Loubry, who tried to contact the minister as soon as the plastics manufacturers association learned of the ban yesterday afternoon. The legislation has now to go to the French Senate. Loubry said he hoped to meet shortly with environment ministry officials to discuss the situation. Plastics Europe, he added, will lobby politicians in both the Assembly and Senate. There is still a chance to block it, but the battle will be tough. This is completely unrealistic and I hope the plastic bag will not be the sacrificial victim of this whole story, Loubry said.

- **Ireland taxes plastic bags**
  - 3 converters forced to close

- **Other State and local legislation to reduce Packaging**
“Could legislation choke US ink making?”*

- Environmental legislation pushes up costs by 10-15%
  - EPA 1990
  - VOC Directive
  - Climate Change Levy
  - Packaging recycling regulations
  - Integrated Pollution Control
  - Hazop regulations
  - REACH Legislation
  - Cost of gaining Sustainability credentials – Life Cycle Analysis
  - Toxicology testing

- Insurance cost increases
- Disincentive to R&D

*Headline in Ink World magazine
What is the FPA doing?
Strategic Focus 2005-2010 for FPA

- Meeting October 3 - 4 determined priorities:
  - Method 25 vs. 25a – inconsistency in VOC emission rates
  - Total Facility Risk Rule
  - Once in always in policy
  - Flexible Permitting
  - Revision to Emission factors AP45
  - Review Stack test document
  - Regulating shop towels and disposable wipes
  - TRI / Ozone Delisting
  - SPCC – Spill Prevention, Control and Countermeasures
  - HCFC phase-out
  - VOC Reactivity – Umbrella monitoring
  - Ozone Transport Commission – control measures for Printing & Graphic Arts
  - EPA response to Title V Task Group

- Future issues will be added as required
Critical Issue Management

- Packaging Waste: US EPA Initiative
  - Flexible packaging well recognized for Source Reduction
  - Packaging waste increasing and focus of US EPA
  - Currently, no federal regulatory mandates on packaging waste
    - Watching European situation
  - EPA willing to partner with industry
  - Industry must take lead on product design and exhibit Product Stewardship by
    - Source Reduction
    - Increased reuse
    - Recyclability
    - Reducing toxic constituents
    - Energy Conservation
  - Minimize environmental impacts of end-of-life packaging to avoid mandates
Critical Issue Management

- **Sustainable Packaging:**
  - The requirements are a true cradle-to-cradle system for all packaging, which includes maximizing the use of renewable or recycled source materials and physical package design to optimize materials and energy.
  - Sustainable Packaging Coalition (SPC) of which US EPA is a member committed to above criteria.
  - Currently, SPC has 158 members and growing.
    - Wide ranging membership from Converters and Suppliers to Brand Owners and Retailers
  - FPA members need to join the Coalition to influence meeting outcomes. The Trade Associations are at present denied entry.
Critical Issue Management

- Registration, Evaluation, Authorization and Restriction of Chemicals (REACH):
  - As the name suggests REACH is a four-part regulatory system. European Parliament adopted REACH proposal, which would cover numerous chemicals including additives, inks and dyes and impact producers of food packaging materials.
  - Intensive lobbying continues on the proposal with anticipated implementation date of 2007.
  - REACH will create regulatory system for chemical approvals in Europe, which has implications for downstream customers and users.
  - International Chemicals Management is under development, which would require risk-based approach for chemicals management.
  - REACH is a huge issue for international businesses.
    - Will add cost and complexity
    - Possible product withdrawals
    - Potential for geographic inequity
Critical Issue Management

- **Food Contact Notification (FCN) Program:**
  - FDA’s proposed budget for FY 2008 calls for discontinuation of the current 120-days FCN approval program for food contact substances (e.g., packaging materials).
  - Over 500 FCNs have become effective since program implementation in August 2000.
  - Each year about 100-125 applications submitted/approved.
  - Program has been extraordinarily successful as FDA review time is cut down to 120-days from 3-5 years under the old petitioning system.
  - It is very important issue for our industry. At least 12-members have used the 120-days approval process.
  - FPA working toward joining the industry coalition to reinstate the funding for the program.
  - If funding is not restored, User Fee is an option for the Program continuation. It will require act of the Congress to structure the program.
  - Need clear direction and members’ involvement to avoid adverse impact on our industry.
Critical Issue Management

- **Toxics in Packaging:**
  - States in the U.S. are now focusing on heavy metals in packaging.
  - Recently, a dietary supplement recalled because the packaging included a battery-powered flashing light with lead solder, an important lesson for global producers.

- **UK Review of MAP Shelf Life Proposal:**
  - Under consideration are revisions to Shelf-Life guidelines in UK for vacuum packaging and modified atmosphere products.
  - Being proposed to limit the shelf life to 5-days from the current 10-days.

- FPA will actively monitor all relevant activity
Support the FPA

- A united voice is a stronger voice
- Protecting our Interests
  - Acting as a pressure group
  - Mutual benefits
- Keeping within the law
  - Protecting our employees
  - Looking ahead to future issues
- Source of competitive advantage
- World Class suppliers
Threat or Opportunity

- Glass half full or half empty?

- It’s up to you!