

# Afera Technical Seminar 2015

Is there impact from chemical regulation to tape industry



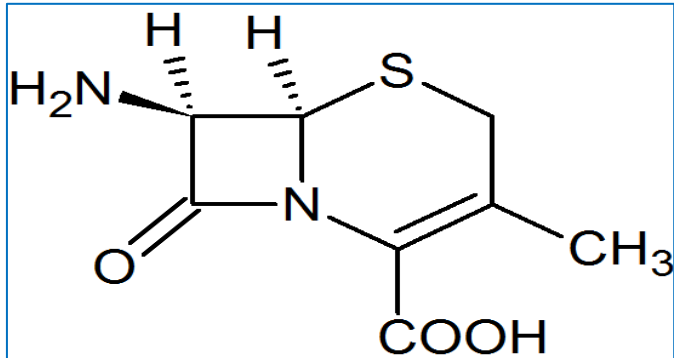
Amy Aerts, Regulatory Affairs manager

# Presentation today...

1. Is there impact of chemical regulation on business today?
2. What were the biggest changes in the regulatory climate?
  - IMDS
  - RoHS
  - REACH
  - ...
3. Are there new changes to expect?
4. How to deal with regulatory issues in your company?
5. Conclusion



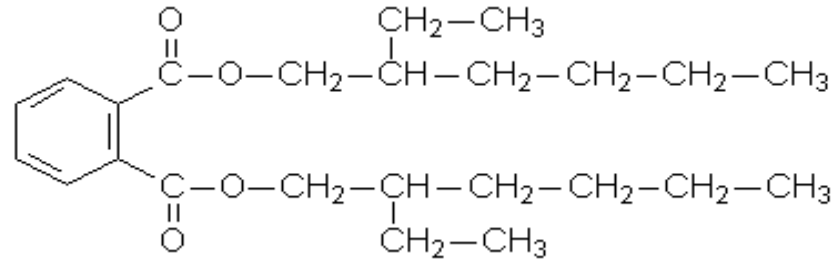
# 1. Is there impact today?



## C,C azodicarbonamide

Blowing agent for PVC, PE and PU, unique properties

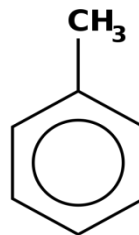
**Already plans to ban this chemical for use in the EU (REACH)**



## DEHP, Bis(2-ethylhexyl) phthalate

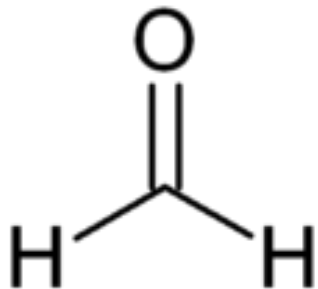
Plasticizer, in the past commonly used

**Banned for use in the EU market (REACH)**



## Toluene

Solvent, commonly used **Already restricted for use in consumer goods (0,1%) + lower TLV**



## Formaldehyde

present in binders and adhesives for wood, carpeting, and other products

**In evaluations (CORAP) and labeled as a known human carcinogen**

## 2. Why was there a change?

- 2000 (IMDS) International Material Data System
- 2005 (GADSL) global automotive declarable substance list
- 2006 (RoHS) or The Restriction of Hazardous Substances Directive 2002/95/EC
- **2008 (REACH) Registration, Evaluation, Authorisation and Restriction of Chemicals**
- 2009 (CLP) Regulation for Classification, Labelling and Packaging
- ... More chemical frameworks in Korea, Malaysia, China, US, Japan,...

# 2.1 IMDS & GADSL (standard)



= Commercial standard no regulation



MDS - MATERIAL DATA SYSTEM - Microsoft Internet Explorer

MATERIAL DATA SYSTEM

MDS and Module Search

Step 1

Component Semi-component Material Basic Substance All MDS/Modules

Name: [ ] Language:  English  German  
Internal Mat.-No.: [ ] Development Sample...: [ ]  
ID-No.: [ ] **Step 2**  
Release date from: [ ] to [ ]  
Supplier: [ ]  
Org.-Unit: [ ]  
Origin:  all  accepted  published  
 own  only Modules  
Org.-Unit: [ ]  
Version:  current  all  
Trade name: [ ]  
Std. Mat.-No.: [ ] Symbol: [ ]  
Norm/Standard: [ ] Search  
Classification: [ ] Search

Search Cancel

Step 3

Compositional data including disclosure of GADSL substances (3126 substances)





## 2.3 RoHS (Directive)



RoHS specifies maximum levels for the following six restricted hazardous substances



lead



cadmium



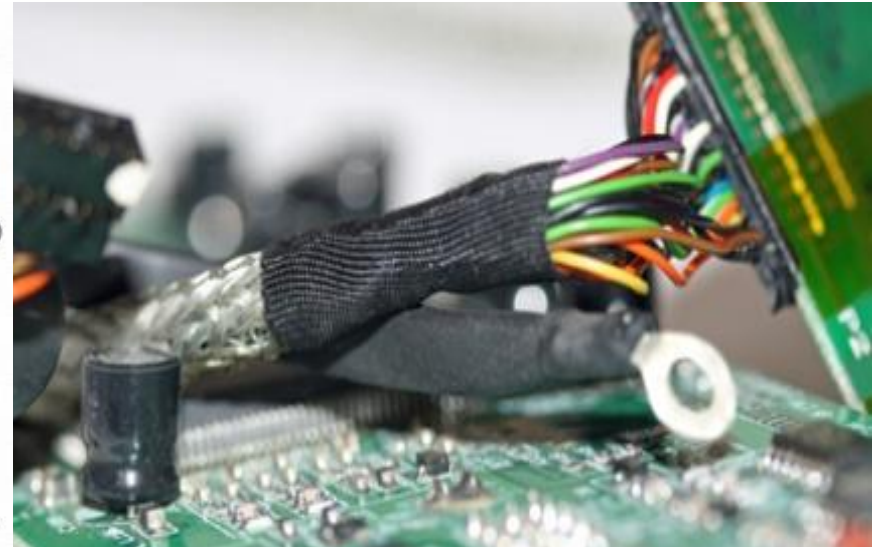
mercury



hexavalent chromium



polybrominated biphenyls  
polybrominated diphenyl ether



### In electric and electronic devices

The RoHS II directive (2011/65/EU) enforced 2/12/2013.

- It requires periodic reevaluations that facilitate gradual broadening of its requirements to cover additional electronic and electrical equipment, cables and spare parts and the chemicals involved
- The CE logo now indicates compliance



## 2.4 REACH (Regulation)

### REGISTRATION



- Obligation for industry
- Import or manufacture substance > 1 ton/year
- Submitting dossier to government regarding uses and an assessment of the hazards and potential risks presented by the substance.
- Cost from 1000k€ to <1M (+ annual cost)

### EVALUATION



- Evaluation by Government and the Member States
- Examination of the quality of the registration dossiers and the testing proposals
- To clarify if a given substance constitutes a risk to human health or the environment.

## 2.4 REACH (Regulation)

### AUTHORISATION



- Substances of Very High Concern will be progressively banned
- The goal is that SVHC are properly controlled and that these substances are replaced by suitable alternatives
- 155 candidates and 31 forbidden
- Temporary authorization is granted for unique application cost 200k€ to 500k€

### RESTRICTION

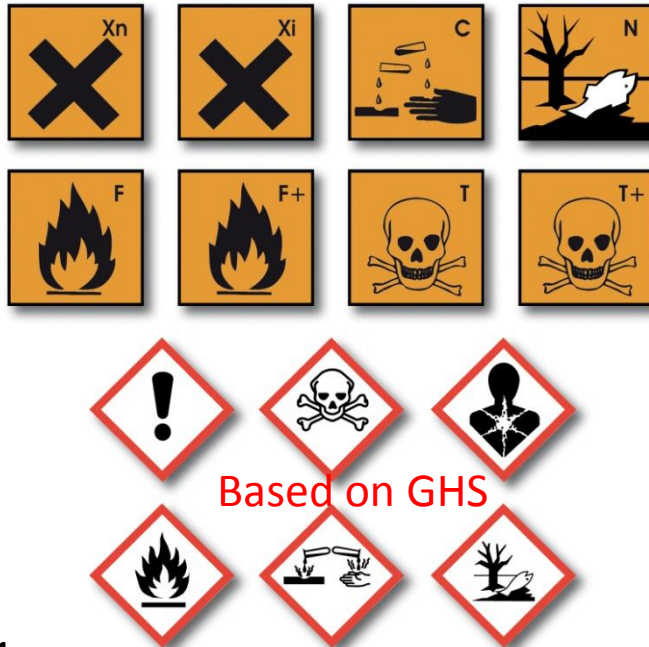


- Restrictions may limit or ban the manufacture, placing on the market or use of a substance.
- A restriction applies to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports.
- Today 60 restrictions in force



# 2.2 CLP (regulation)

2



Based on GHS

1

**Polytek**  
Development Corp.

**SAFETY DATA SHEET**

**1. Identification**  
Product Identifier: Poly 74-20 Liquid Rubber Part B  
Poly 74-24 Liquid Rubber Part B  
Poly 74-29 Liquid Rubber Part B  
Poly 74-30 White Liquid Rubber Part B  
Poly 74-30 Liquid Rubber Part B  
Poly 74-30 Clear Liquid Rubber Part B  
Poly 74-30 HT Liquid Rubber Part B  
Poly 74-31 Liquid Rubber Part B  
Poly 74-41 Liquid Rubber Part B  
Poly 74-45 Liquid Rubber Part B  
Product Code(s): 74-20B, 74-24B, 74-29B, 74-29WHITER, 74-30B, 74-30CLEARB, 74-30HTB, 74-31B, 74-41B, 74-45B  
Use: Component for Polyurethane Mold Rubber For Industrial/Professional use only  
Manufacturer: Polytek Development Corp. 55 Hilton St., Easton, PA 18042 USA  
Phone Number: +1 610-559-8020 (9 a.m. to 5 pm EST)  
Emergency Phone: CHEMTREC: 800-424-9300 or +1 703-527-3387  
E-mail: sds@polytek.com

**2. Hazard Identification**  
GHS Classification: Specific Target Organ Toxicity - Repeated Exposure Category 3  
Label Element: Warning!

Contains Diethyltoluenediamine

**Hazard Phrases**  
H373 May cause damage to pancreas through prolonged or repeated exposure.

**Precautionary Phrases**  
P260 Do not breathe vapors  
P314 Get medical advice if you feel unwell.  
P501 Dispose of contents and container to licensed, permitted incinerator, or other thermal destruction device in accordance with local and national regulations.

**Supplemental Information:** None known.  
This is one part of a two-part system. Read and understand the hazard information on Part A before using.

**3. Composition/Information on Ingredients**

Chemical Name	CAS #	%
Diethyltoluenediamine	68479-92-1	1-3%

**4. First-Aid Measures**  
**Eye Contact:** Flush thoroughly with water, holding the eyelids open to be sure the material is washed out. Get medical attention if irritation persists.  
**Skin Contact:** Remove contaminated clothing. Wash contact area thoroughly with soap and water. Get medical attention if irritation persists.  
**Inhalation:** Remove person to fresh air. Get medical attention if symptoms persist.  
**Ingestion:** Do not induce vomiting unless directed to do so by medical personnel. Get medical attention.

**Most Important Symptoms/Effects:** May cause mild eye and skin irritation. May be harmful if swallowed.  
**Indication of Immediate Medical Attention/Special Treatment:** Immediate medical attention is not required.

**5. Fire-Fighting Measures**  
**Extinguishing Media:** Use water fog, foam, carbon dioxide or dry chemical. Do not use solid water stream. Solid stream of water into hot product may cause violent steam generation or explosion.  
**Specific Hazard:** Not classified as flammable or combustible. Product will burn under fire conditions.  
**Special Protective Equipment & Precautions for Fire-Fighters:** Wear positive pressure, self-contained breathing apparatus and full-body protective clothing. Cool fire-exposed containers with water.

**6. Accidental Release Measures**  
**Personal Precautions, Protective Equipment and Emergency Procedures:** Remove all ignition sources. Clear non-emergency personnel from the area. Wear appropriate protective clothing to prevent eye and skin contact and avoid breathing vapors. Contain - spill area may be slippery.  
**Methods and Materials for Containment and Cleanup:** Cover with an inert absorbent material and collect into an appropriate container for disposal. Avoid releases to the environment. Report spills and releases as required to appropriate authorities.

**7. Handling and Storage**  
**Safe Handling:** Use with adequate ventilation. Avoid contact with the eyes, skin and clothing. Wash thoroughly after handling. Do not eat, drink or smoke in the work area. Keep container closed when not in use.  
**Safe Storage:** Store indoors at temperatures below 120°F (49°C). Store in original containers. Avoid getting moisture into containers. Keep containers tightly closed.

**8. Exposure Controls/Personal Protection**  
**Occupational Exposure Limits:** None Established  
**Ventilation:** Use with adequate general or local exhaust ventilation to minimize exposure levels.  
**Respiratory Protection:** If needed, an approved respirator with organic vapor cartridges may be used. Respirator selection and use should be based on contaminant type, form and concentration. For higher exposures or in an emergency, use a supplied-air respirator.  
**Skin Protection:** Wear impervious gloves, such as butyl rubber or nitrile rubber.  
**Eye Protection:** Wear chemical safety goggles.  
**Other Protective Measures:** Wear impervious clothing to prevent skin contact and contamination of personal clothing. An eye wash facility and washing facility should be available in the work area. Follow applicable regulations and good Industrial Hygiene practice.

**9. Physical and Chemical Properties**  
**Appearance:** Liquid of varied colors  
**Odor:** Slightly pungent  
**Color:** Threshold: No data available  
**pH:** Not applicable  
**Boiling Point:** No data available  
**Freezing Point:** No data available  
**Flash Point:** ~ 350°F (~177°C)  
**Evaporation Rate:** No data available  
**Upper/Lower Flammability Limit:** No data available  
**Vapor Pressure:** ~ 0.01 mm Hg @ 25°C  
**Vapor Density:** No data available

Data Prepared/Revised: Dec. 6, 2013; Supersedes: April 3, 2013  
SDS NUMBER: P101-101-101-101-101-101

Updated Polytek® Safety Data Sheet [Page 1 Only]

3 C&L notification the creation of a classification and labeling inventory.

**Polytek**  
Development Corp.

www.polytek.com • 610.559.8620  
55 Hilton St. - Easton, PA 18042

**Poly 74-20 Liquid Rubber Part B**

**DIRECTIONS:** Before use, read Technical Bulletin and SDS. Mix ratio by weight is 1A to 2B. Shake or stir Part B thoroughly before use. Combine proper amounts of A and B in a clean mixing container. Mix well, thoroughly scraping sides and bottom repeatedly. Pour over a properly prepared model as soon after mixing as possible. Pour time is 30 minutes. Demold after ~24 hours at room temperature. Close container tightly after use.

**CONTENTS:** Polyol, Diethyltoluenediamine, and trade secret ingredients  
**NET WEIGHT:** 40 lb  
**FOR INDUSTRIAL/PROFESSIONAL USE ONLY.**  
**MADE IN THE USA**

**WARNING: MAY CAUSE DAMAGE TO ORGANS (PANCREAS) THROUGH PROLONGED OR REPEATED EXPOSURE.**

Do not breathe vapors. Get medical advice if you feel unwell. Dispose of contents and container to licensed, permitted incinerator, or other thermal destruction device in accordance with local and national regulations.  
**SUPPLEMENTAL INFORMATION:** This is one part of a two-part system. Read and understand the hazard information on Part A before using.

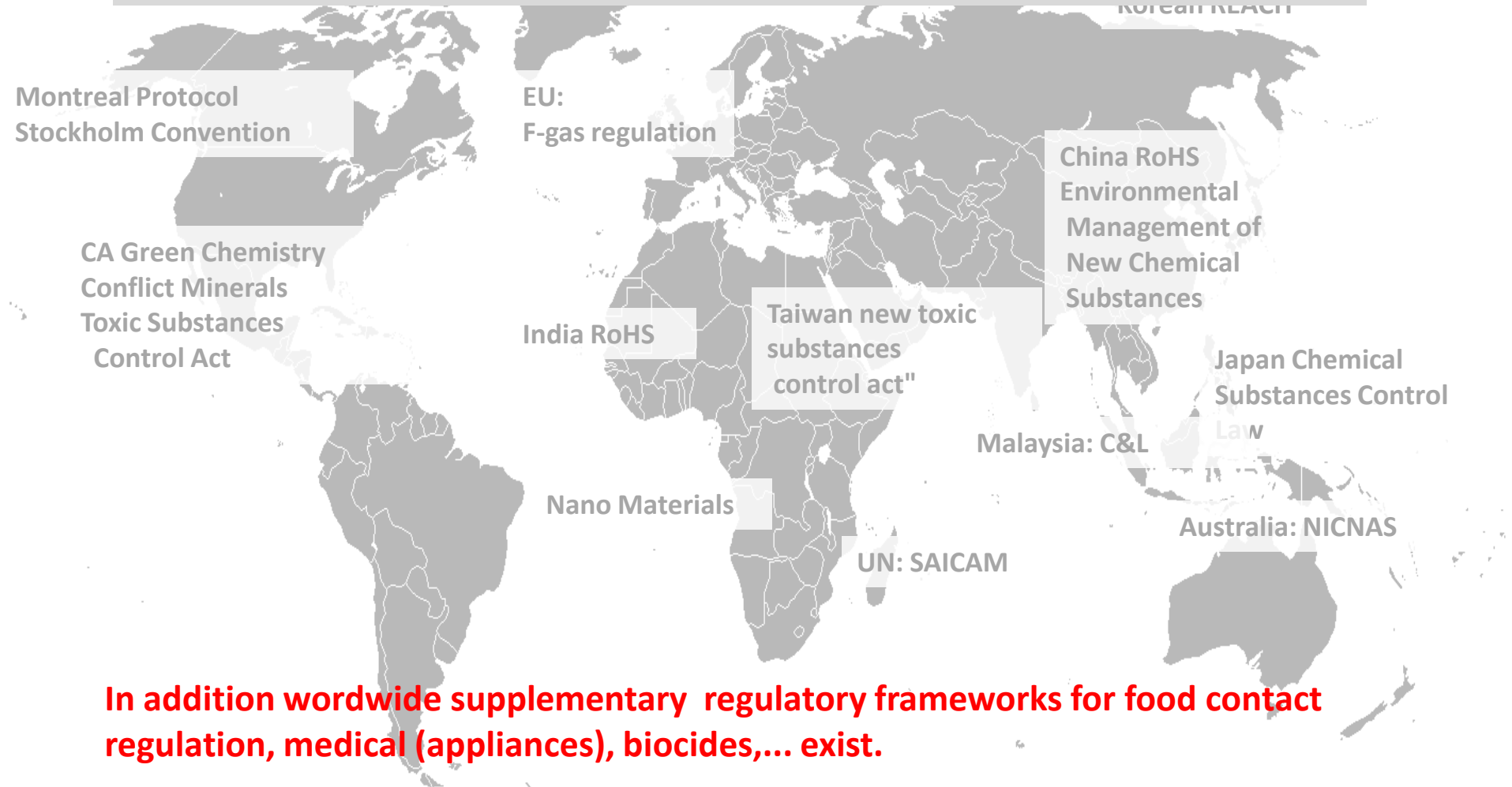
DISCLAIMER: The information contained herein is considered accurate; however, Polytek® makes no warranty regarding its accuracy. The user must determine the suitability of the product for the intended use and accepts all risk and liability associated with that use.

1234567 7420840

Updated Polytek® Product Label [Poly 74-20 Liquid Rubber: Part B]

## 2.5 Global regulation

**new (substance) will be banned or restricted. More countries will adopt a chemical regulation.**



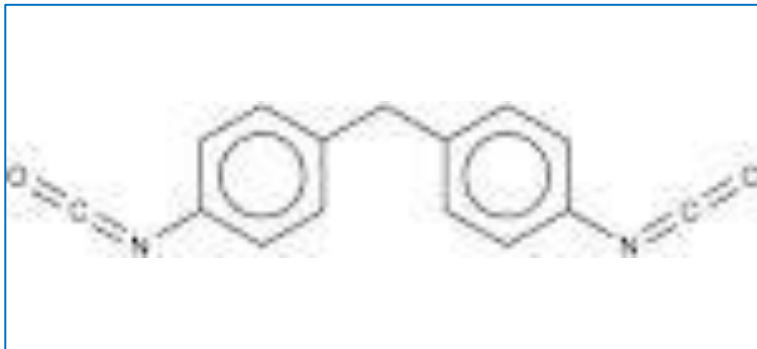
**In addition worldwide supplementary regulatory frameworks for food contact regulation, medical (appliances), biocides,... exist.**

### 3. Chemical regulation to be expected

- EU-wide commitment to include **all relevant currently known substances of very high concern** (SVHCs) included in the Candidate List by 2020.
- This is part of the authorisation process of REACH to ban substances and promote substitution.
- Called **SVHC roadmap**



### 3. Chemical regulation to be expected



methylene diphenyl diisocyanate (MDI)

crosslinker

**REACH restriction + Danisch undesirable list  
Chemicals Management Plan (Canada)  
(cooperation with EU)**

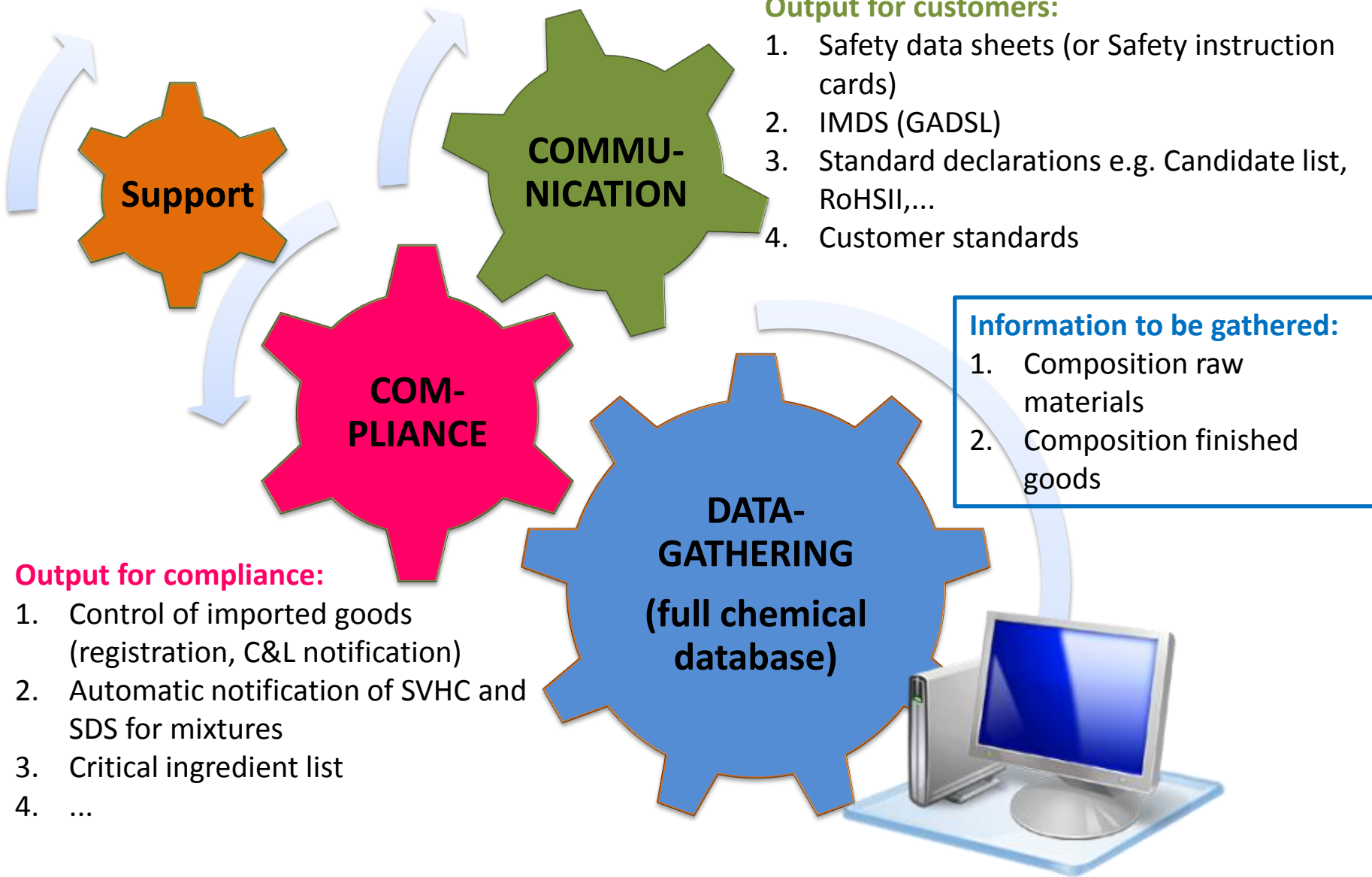
Registration of polymers



Strategy of European Commission, DG Environment for 2015, 2020 and beyond (Head of Unit: Chemicals Bjorn Hansen)

- 2015: Ensure safety of Nano, minimisation of exposures to EDs, appropriate regulatory approaches to mixtures minimization of exposures to substances in articles.
- 2018: Develop an EU Strategy for a non-toxic environment, that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions

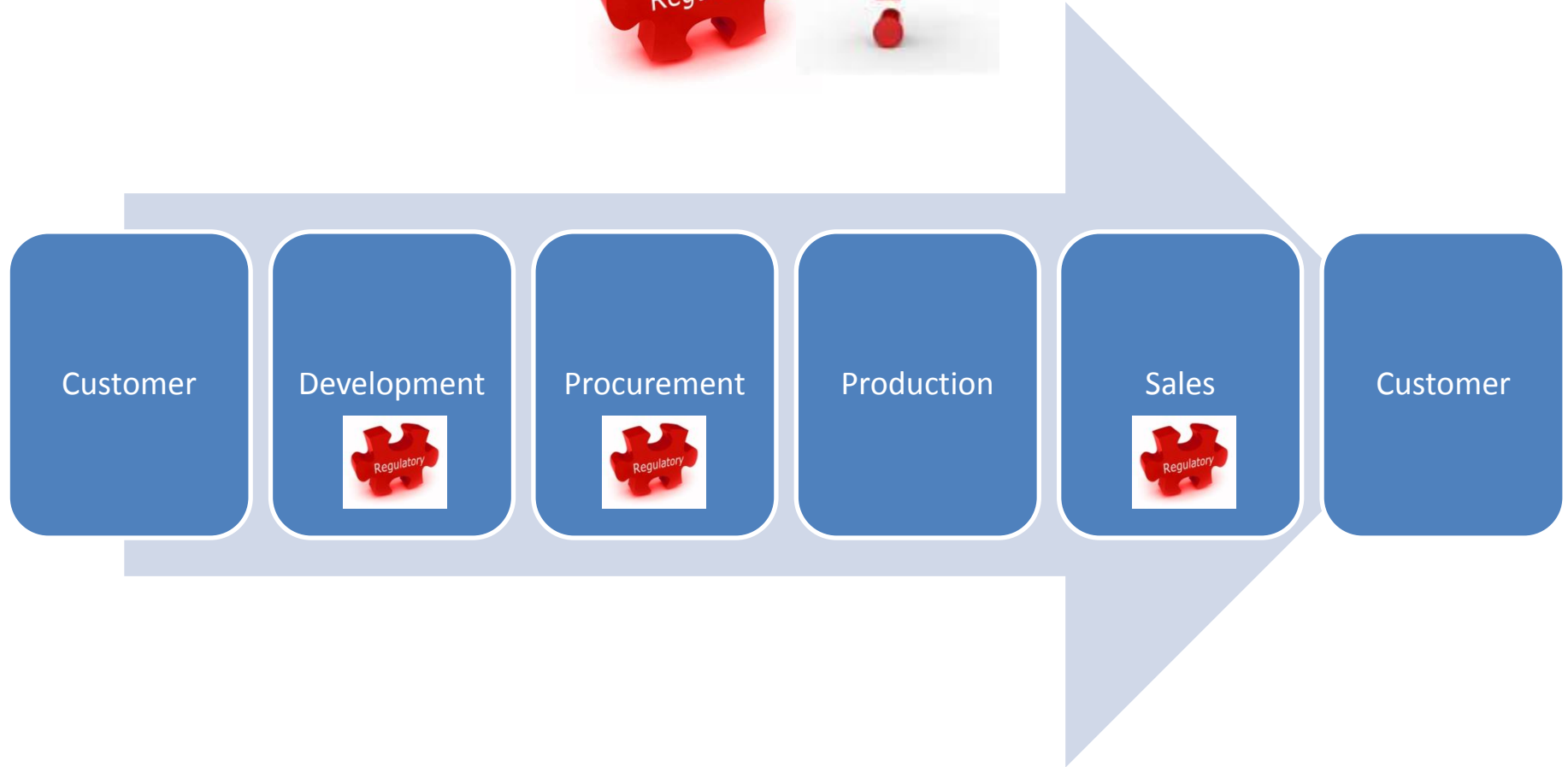
# 4. How can we cope?



## Output for compliance:

1. Control of imported goods (registration, C&L notification)
2. Automatic notification of SVHC and SDS for mixtures
3. Critical ingredient list
4. ...

# 4. How can we cope?





# 4. How can we cope?



# How can we cope?

## Regulatory affairs:

- Need to be handled in organisation by specialised department:
  - Seperate department (Regulatory Affairs, product stewardship, ...)
  - Part of another department
- A system with compositional data is required
  - Create critical ingredient list
- Needs to support development, business development, other related departments (e.g. Sustainable development)
- For international companies regulatory support of each region is important

# Conclusion

- Chemical regulation is very complex today
- Regulatory affairs will increase in importance due to the increasing substances affected by chemical regulation
- It is clear regulatory issues can have impact on business
- To adapt the organisation to these requirements is key



