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Choose certainty.  
Add value.

# International Regulatory Requirements - A Consultative Approach

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Ambur Open -2011/07/09-10

TÜV SÜD



# The Situation now



**CPSIA**

**EN**

**?**

**CALPROP 65**

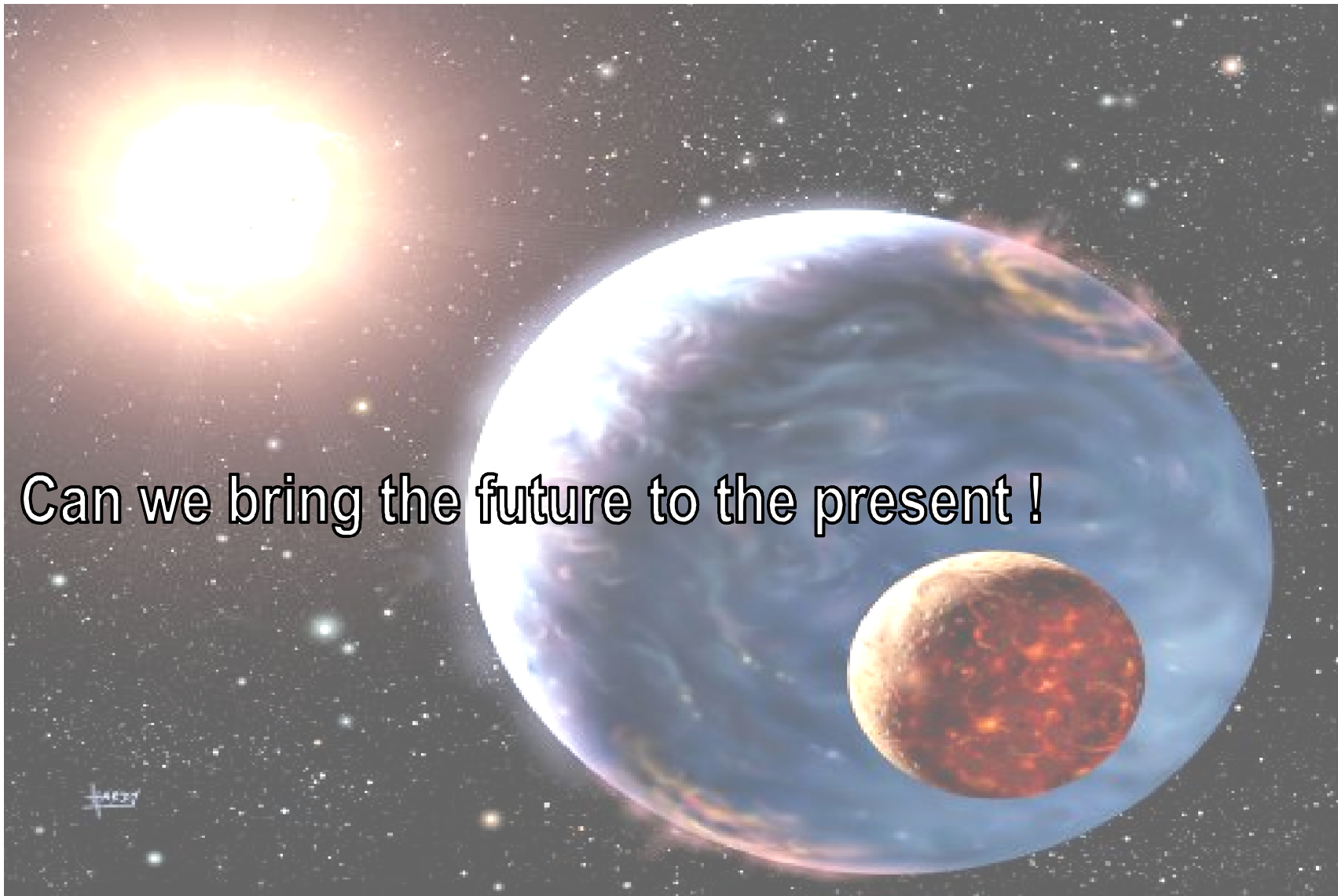
**UNIFIED REQUIRMENTS ???**

**??**

**ANNEX XVII**

**SVHC**

# The Shift



Can we bring the future to the present !



## Regulation (EC) No 1907/2006 REACH

(the **R**egistration, **E**valuation, **A**uthorisation and restriction of **C**hemicals)

- § A single, coherent system that amends and replaces 40 existing chemical legislations.
- § Aims to protect the human health and the environment from the adverse effects of dangerous chemicals.
- § It places the responsibility onto the EU manufacturers and EU importers to ensure the chemicals that are put on the EU market do not adversely affect human health or the environment.
- § Consumer products are also under control.
- § REACH cannot place any direct obligations on non-EU entities.





## Regulation (EC) No 1907/2006 REACH

(the **R**egistration, **E**valuation, **A**uthorisation and restriction of **C**hemicals)

### 1. Registration

- § substances on their own
- § substances in mixtures
- § substances in articles in case of intended release
- § Only Representative (OR)

### 2. Evaluation

- § dossier evaluation
- § substance evaluation
- § testing proposal evaluation

### 3. Authorisation

- § Substances of Very High Concern (SVHC)
- § Candidate List
  - § communication along supply chain
  - § notification
- § Annex XIV (“the Authorisation List”)
  - § authorisation

### 4. Restriction

- § hazardous chemicals
- § general ban or product specific
- § from Directive 76/769/EEC to Annex XVII

Substance = Chemical

Substance



eg. calcium chloride  
(a common household  
desiccant )

Substance  
in **mixture**



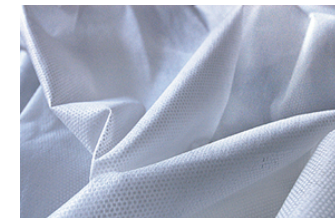
eg. washing powder

Substance  
in **article**



eg. Shoe

Substance  
in **article intended to be  
released**



eg. fabric with a  
microencapsulated chemical

**Article** – an object which during production is given a **special shape, surface or design** which determines its function to a greater degree than does its chemical composition

# Also considered as articles



# Who is responsible for REACH for imports?



Customs Border

Upstream



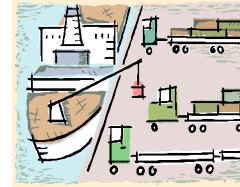
Non-EU  
Substance  
Manufacturer



Non-EU  
Mixture  
Formulator



Non-EU  
Article  
Producer



EU  
Importer



EU  
Distributor



EU  
Retailer

Downstream

## Article 33 (1, 2):

If an article contains any SVHC on the Candidate List at  $> 0.1\%$  w/w



**Immediately** inform the recipient the following information



Consumers have the right to **request** SVHC information on a product, and the following information must be provided within **45** days

- the name of the SVHC
- any instruction for the safe use of the product, if available

No specified methods on how this information must be communicated.  
Packaging materials are also defined as articles.



# Who communicates SVHC information?



Customs Border

Upstream



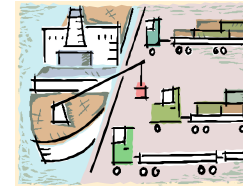
Non-EU  
Substance  
Manufacturer



Non-EU  
Preparation  
Formulator



Non-EU  
Article  
Producer



EU  
Importer



EU  
Distributor



EU  
Retailer

Downstream



Non-EU suppliers communicate SVHC information based on business decisions.



Retailers communicate SVHC information only upon request by consumers.

# Restriction vs Candidate List



Restriction	Candidate List (SVHC)
§ an individual limit per restricted substance	§ a general 0.1% w/w limit applies to all product types
§ limit applies to specified products	§ limit applies to all product types
§ limit is calculated as specified	§ limited is a calculated average for the whole product (except the 7 dissenting countries may interpret different)
§ a product with a restricted substance above the limit may not be placed on the market	§ a product with a Candidate List SVHC above 0.1% w/w can be placed on the market, but supply chain communication requirement applies
<p>Examples:</p> <ul style="list-style-type: none"> <li>○ azocolourants &amp; azodyes (0.0030%, whole product or dyed parts)</li> <li>○ DEHP, DBP, BBP (sum • 0.1%, plasticised parts)</li> </ul>	<p>Examples:</p> <ul style="list-style-type: none"> <li>○ 4,4'-diaminodiphenylmethane (MDA) (• 0.1% w/w)</li> <li>○ DEHP, DBP, BBP (each phthalate • 0.1% w/w)</li> </ul>

# CPSIA – An Overview



# What is CPSIA?



“To establish consumer product safety standards and other safety standards for children’s and to re- authorize and modernize the consumer product safety commission”

- Introduced Nov. 1, 2007
- Scheduled for Debate Dec. 18, 2007
- Passed House Dec. 19, 2007
- Passed Senate Mar. 6, 2008
- Differences Resolved Jul. 31, 2008
- Signed by President Bush Aug. 14, 2008

# Why CPSIA became Law?



- § Huge Recalls & Public concerns
- § Lead paint has been regulated on toys since 1978.
- § Approximately about 28,000 deaths each year related to unsafe products in the United States.
- § Estimated 33 million people were injured from unsafe products in 2007.





A “Consumer Product” means any article, or component part thereof, produced or distributed:

- For sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.
- For the personal use, consumption or enjoyment of a consumer, in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.



- § Avoid recalls due to substantial product hazards
- § Avoid civil Penalties for failing to comply with a mandatory standard.



## **TITLE I - CHILDREN'S PRODUCT SAFETY**

Sec. 101. Children's products containing lead; lead paint rule.

Sec. 102. Mandatory third party testing for certain children's products.

Sec. 103. Tracking labels for children's products.

Sec. 104. Standards and consumer registration of durable nursery products.

Sec. 105. Labeling requirement for advertising toys and games.

Sec. 106. Mandatory toy safety standards.

Sec. 107. Study of preventable injuries and deaths in minority children related to consumer products.

Sec. 108. Prohibition on sale of certain products containing specified phthalates.

## 102 - Who Must Certify?



§ Every manufacturer/importer or private labeler of a product subject to a CPSC rule and whose product is “imported for consumption or warehousing” or “distributed in commerce”

§ Testing data can be shared by importers and foreign manufacturers for the same product , for the purpose of issuing certificates if :

- Test records are in English and a copy is kept in the US
- The importer is a resident of the US or has a resident agent

# 101 - Lead in Substrate



Total lead content by weight for any accessible part of a Children's Product:

Lead in	Substrate	Lead in	Paint
Limit	Date	Limit	Date
600 ppm	Feb 10 2009	600 ppm	Before Aug 14 2009
300 ppm	Aug 14 2010	90 ppm	After Aug 14 2009
100 ppm	Aug 14 2011		

§ If 100 ppm is not technologically feasible, CPSC will set the lowest possible limit (less than 300ppm) by Aug 2011.

§ Periodic review and further reduction as technologically feasible.

*3<sup>rd</sup> Party Testing Requirement and GCC Requirement for Lead in Children's & Non Children's Products is now postponed from Feb 10<sup>th</sup> 2011 to Dec 31<sup>st</sup>, 2011.*





**UNITED STATES  
CONSUMER PRODUCT SAFETY COMMISSION  
DIRECTORATE FOR LABORATORY SCIENCES  
DIVISION OF CHEMISTRY  
10901 DARNESTOWN RD  
GAITHERSBURG, MD 20878**

**Test Method: CPSC-CH-C1001-09.3  
Standard Operating Procedure for Determination of Phthalates  
April 1<sup>st</sup>, 2010**

This document provides detailed information on test methods that will be used by the U.S. Consumer Product Safety Commission's (CPSC) testing laboratory (LSC) for the analysis of phthalate content in children's toys and child care articles covered by the standard set forth in the Consumer Product Safety Improvement Act Section 108.

It has been concluded that in order to protect children from the hazard the Act intended to address, that "concentrations of more than 0.1 percent" must apply per plasticized component part of a children's toy or child care article<sup>1</sup>.

# Small Parts Rule



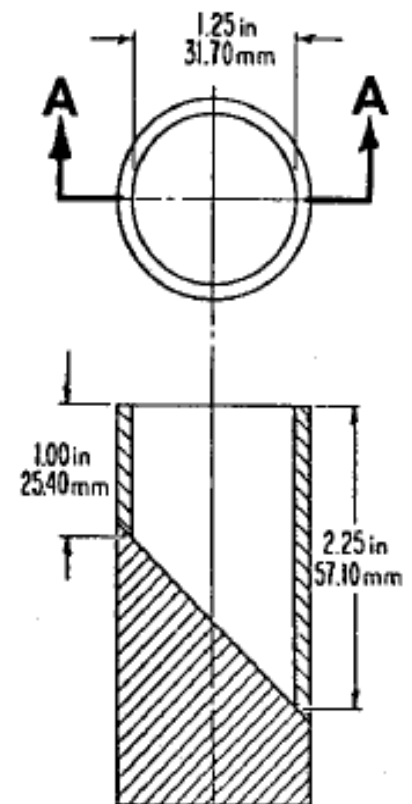
16 CFR 1501 – Covers products that are intended for use by children under three, including toys, dolls, nursery equipment, infant furniture and equipment.

A small part can be:

- A whole toy or article
- A separate part of a toy, game, or other article
- A piece of a toy or article that breaks off during testing that simulates use or abuse by children.

Requirement:

Use of a test cylinder stimulating the size of the fully expanded throat of a child under 3 years old. If a small part fits completely into the cylinder, the toy or product (for children under 3 years old) which the small part came from is banned.



Small Parts Test Fixture



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**Choose certainty.  
Add value.**

# California Proposition 65: An Overview

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# What is Proposition 65?



## Safe Drinking Water and Toxic Enforcement Act of 1986 (better known by its original name of Proposition 65)

- An initiative enacted to address citizens' growing concerns about exposure to toxic chemicals.
- Administered by the Office of Environmental Health Hazard Assessment (OEHHA)
- Under the Proposition 65 program,
  - a.The State is required to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm.
  - b.Requires businesses to inform citizens about exposures to (products as well as in the form of releases into the environment) such toxic chemicals enabling them to make informed decisions to safeguard themselves.

# Commonly Debated Chemicals & Toxins



- Lead
- Chloroform
- Phthalates
- PCBs
- Toluene
- Crystalline Silica
- Mercury
- Cadmium
- Formaldehyde
- DEHP
- Asbestos



\* There are currently more than 850 chemicals on the Proposition 65 list.



# Implications of a Proposition 65 Warning



When a Proposition 65 warning is issued, it can mean one of the following:

- The business has evaluated the exposure and has concluded that it exceeds the Safe Harbor Level
- The business has chosen to provide a warning simply based on its knowledge about the presence of a listed chemical without attempting to evaluate the exposure.



# How are Exposures Measured?



- Exposures can be
  - a. Oral
  - b. Inhaled
  - c. Dermal (through the skin)
  - d. Hand-to-mouth
- Exposure (in micrograms/day) is the key factor
- NOT concentration of the chemical (micrograms per liter or parts per million)
- Average use can be debated (battle of experts in court)



# Our approach - Common Criteria Measure



PARAMETERS	EN	REACH/ Annex-XVII	CPSIA	CALPROP 65
BANNED ARYL AMINES (AZO DYES)	.	.		
CHLORINATED PHENOLS	.	.		
PHENOLIC COMPOUNDS - OTHERS (np, op, opp etc.)	.	.		
PHthalATES	.	.	.	.
FLAME RETARDANTS	.	.		
ORGANOTIN COMPOUNDS	.	.		
POLYCYCLIC AROMATIC HYDROCARBONS	.	.		
PESTICIDE RESIDUES / BIOCIDES	.	.		
VOLATILE ORGANIC COMPOUNDS	.	.		
OTHERS				
PFOS	.	.		
METALS				
EXTRACTABLE HEAVY METALS	.			
LEAD - TOTAL	.	.	.	.
LEAD SURFACE COATING	x	x	.	x
LEAD & ITS COMPOUNDS	.	.	.	.
CADMIUM - TOTAL	.	.	.	.
COBALT & ITS COMPOUNDS		.		
CHROMIUM - TOTAL	.	.		
ARSENIC, & ITS COMPOUNDS	.	.		
CHROMIUM COMPOUNDS		.		
BORON & ITS COMPOUNDS		.		
STRONTIUM & ITS COMPOUND		.		
HYDRAZINE		.		
PYRROLIDINE COMPOUND		.		



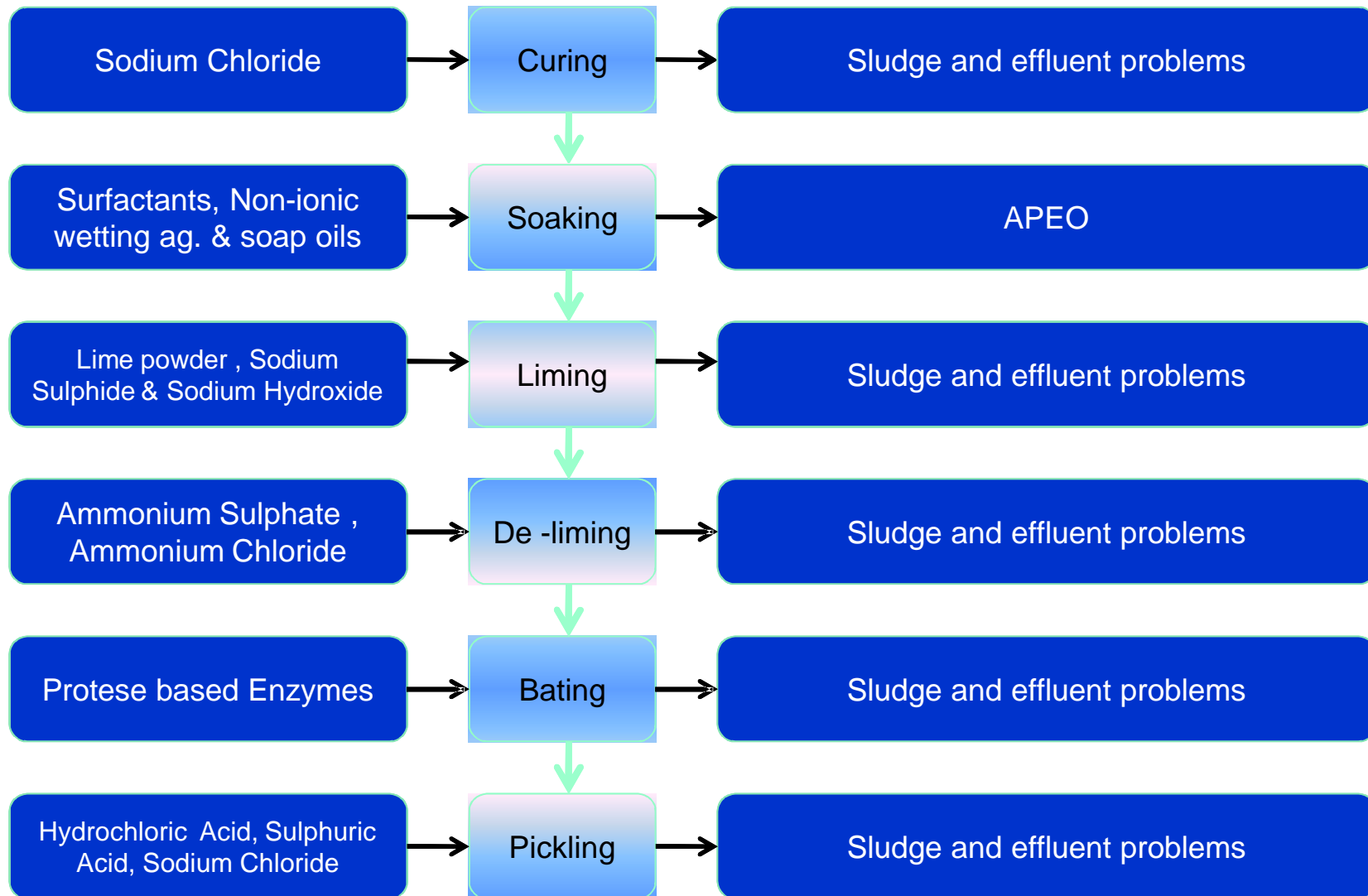
## Create Knowledge Base

S.No	Type of Information	Source of Information
1	Raw Material Use	Raw material purchases , product comparison and batch sheets, <a href="#">MSDS</a> , vendor information, inventory records
2	Production Information	Operating procedures, production schedules, flow diagrams, <a href="#">quality control guidebooks</a> , water and energy usage
3	Regulatory Information	<a href="#">Environmental audit reports, solid and liquid waste disposal records, laboratory analysis</a> , licenses, <a href="#">changes in the regulations</a>
4	Financial Information	Costs for products, energy, water, raw materials and labour, operating costs for waste handling and disposal
5	Commercial Information	Retailers, buyer details along with the specifications

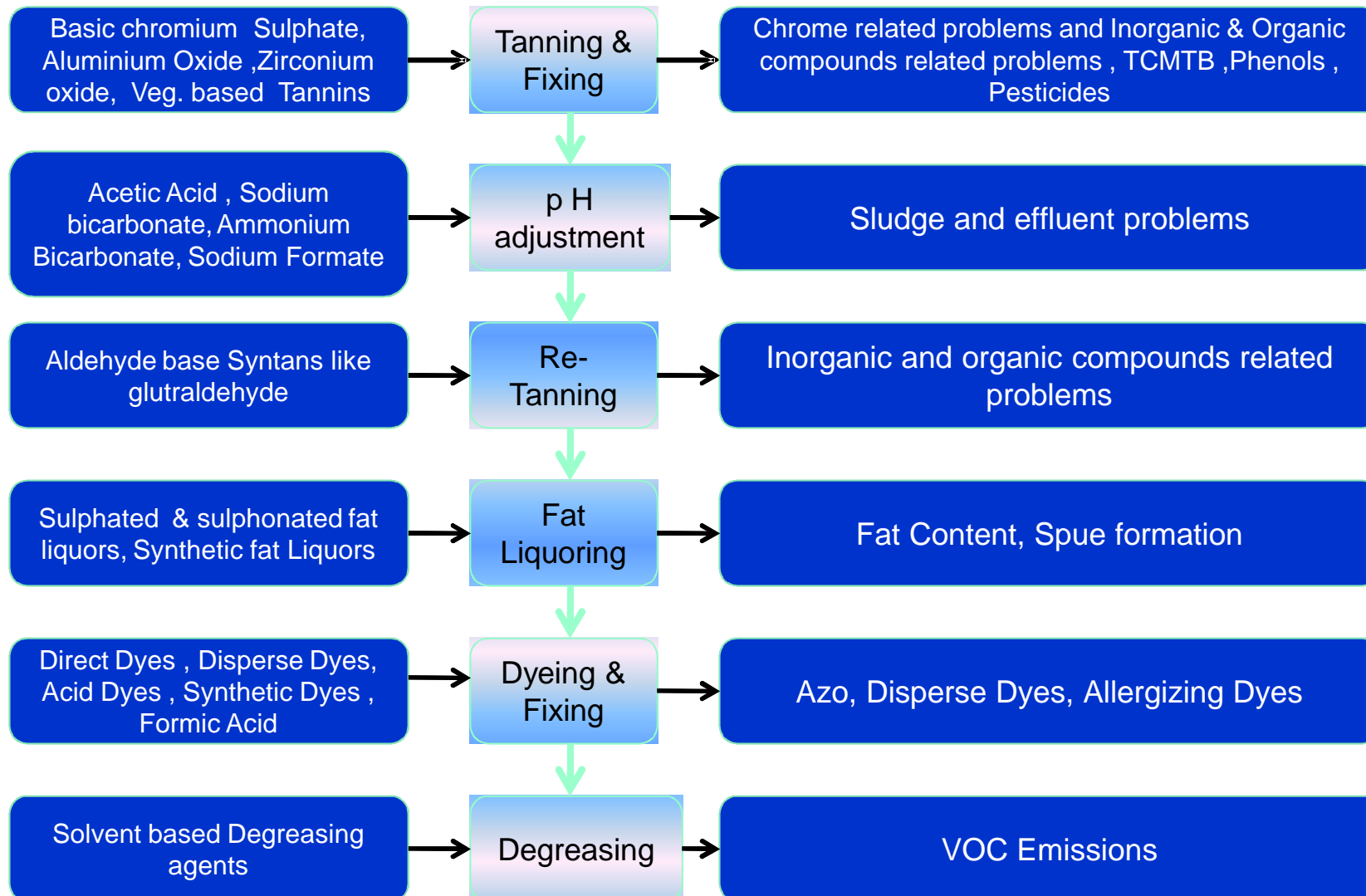
# How..??



## Process Flow – Wet End Process



# How..??





## ü Action Plan for Phase out

- ü Identify each and every chemical & dye used
- ü Obtain MSDS
- ü Seek alternate sources of supply when no MSDS is available
- ü Identify the hazardous chemicals
- ü Ear mark the acceptable substitutes
- ü Product quality assessment
- ü Actual substitution







## Unified Criteria

- Effective Control
- Better Market
- Easy Management
- Better World for the future



# Thank You

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