Global
Sustainability
Summit

UNCOVER THE POSSIBILITIES

Green Chemistry

GMA FMI SUSTAINABILITY SUMMIT
AUGUST 15. 2013

CHEMISTRY THAT MATTERS™

Who Is SABIC ?

How Is SABIC Approaching Sustainability ?

What Processes Are Applied to Product Safety ?

WHO IS SABIC ?

SABIC: SAUDI BASIC INDUSTRIES CORPORATION

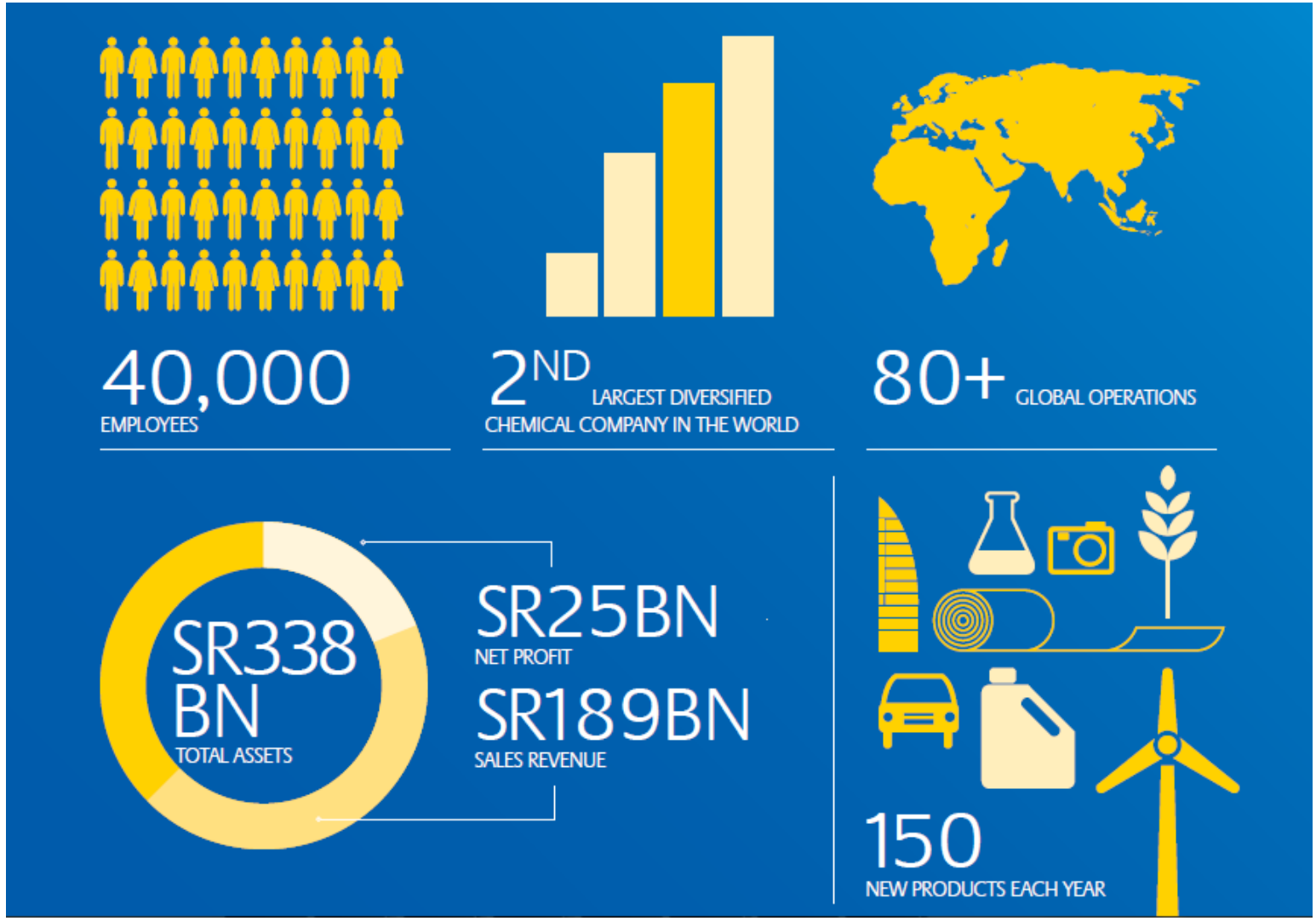
1976

2012

- **Chemicals**
- **Fertilizers**
- **Metals**
- **Polymers**

Global Supplier of Vital Chemicals and Materials for Society

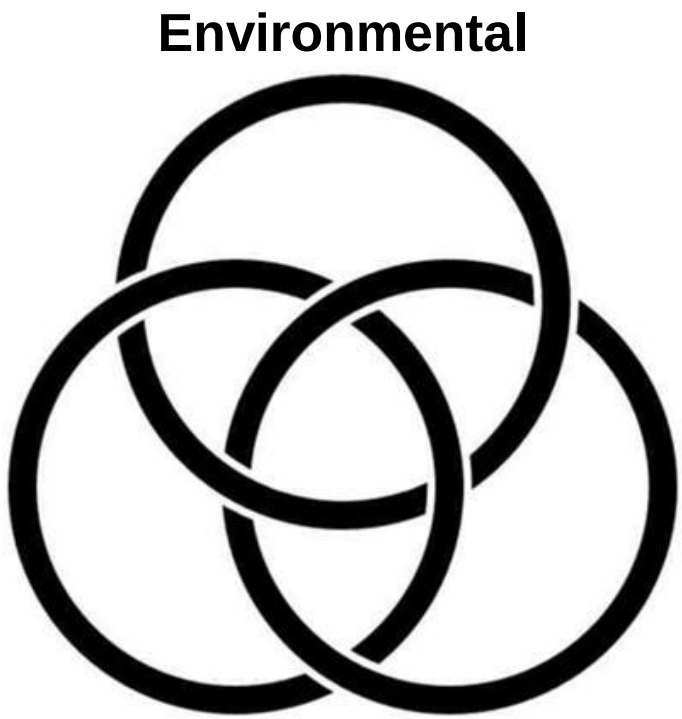
SABIC: KEY FACTS

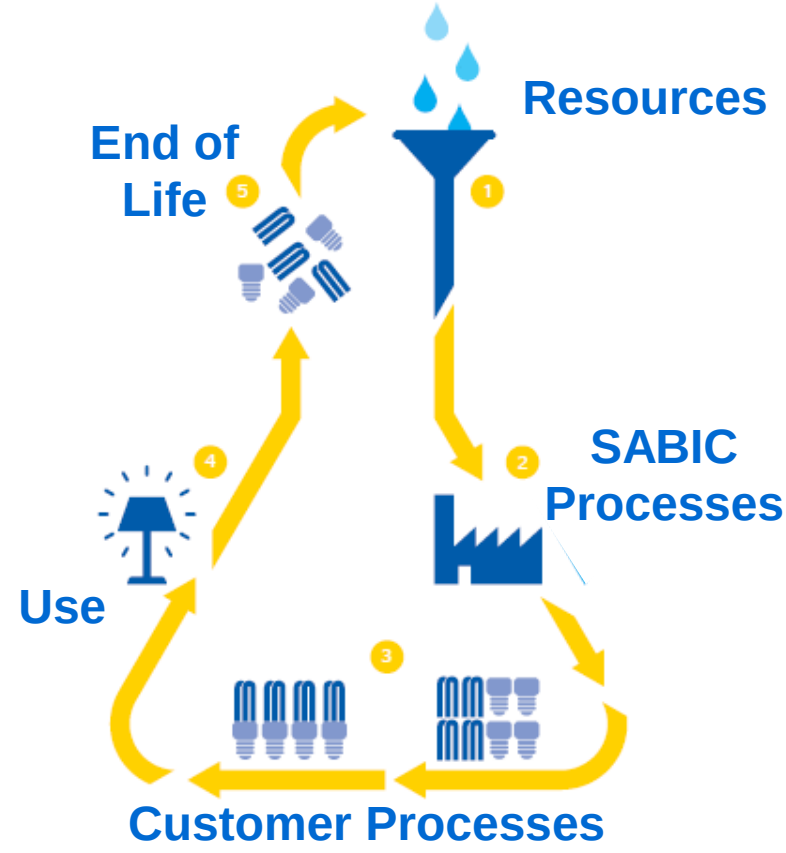


SUSTAINABILITY IN SABIC

SABIC: APPROACH TO SUSTAINABILITY

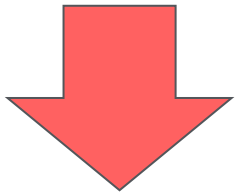
3 Elements of Sustainability Coupled to the Life Cycle



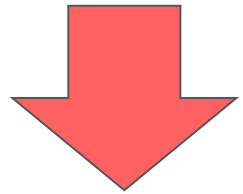


KEY ACTIONS ACROSS THE LIFE CYCLE

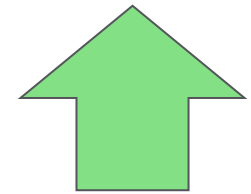
Finite Material Usage



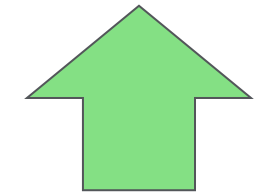
Environmental Footprint



Enable Society to Operate Sustainably



Close the Life Cycle

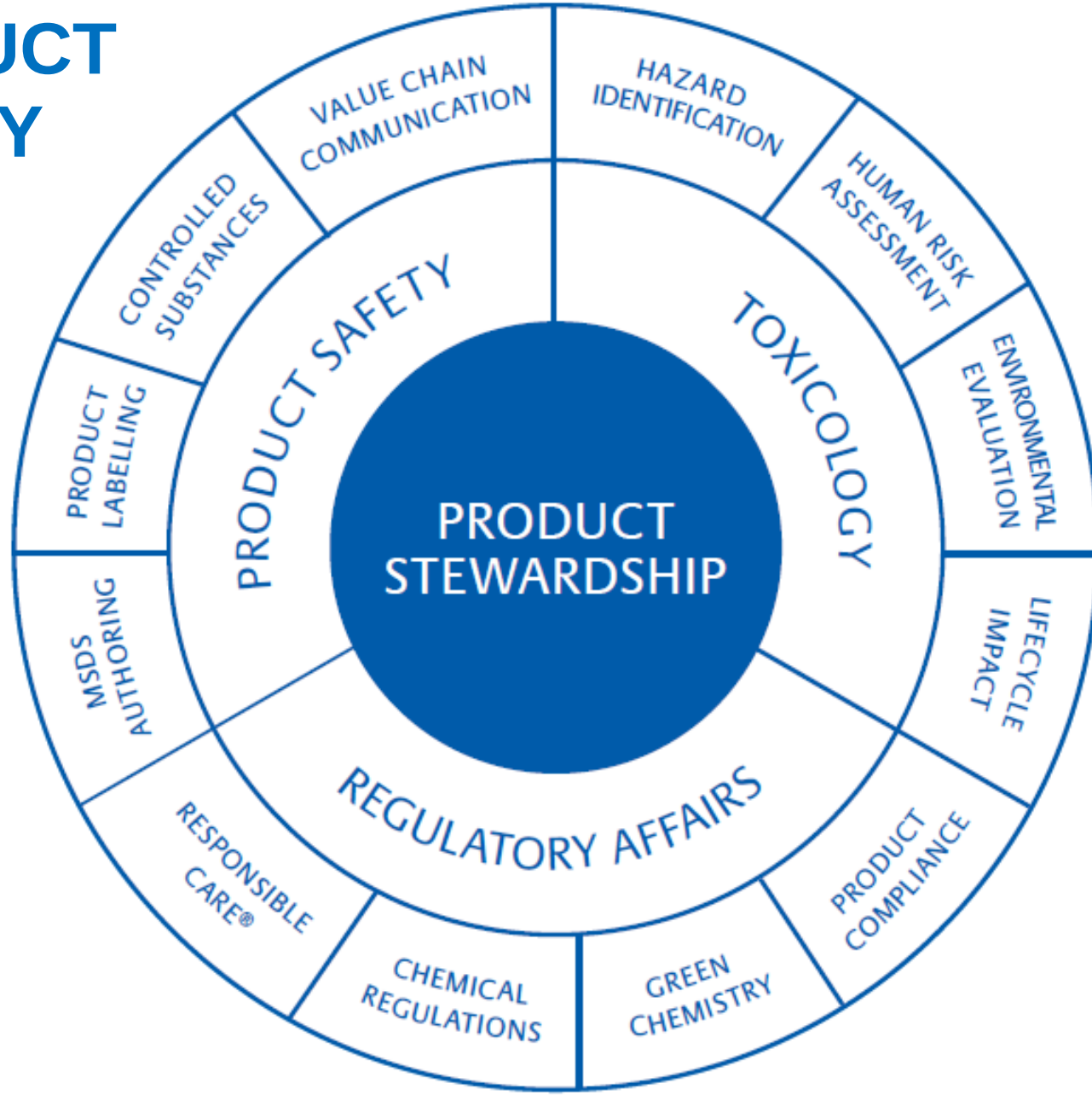


Maximize Value

PRODUCT SAFETY KEY EXPECTATION

ASSURANCE OF PRODUCT SAFETY IS AT THE TOP OF SABIC's AND OUR STAKEHOLDER EXPECTATIONS

PRODUCT SAFETY



PRODUCT SAFETY ASSURANCE STAKEHOLDERS

ASSOCIATIONS

-American Chemistry Council, CEFIC, GPCA
- WBCSD, ICCA
- Sustainability Consortium

REGULATORS

- REACH (EU, China, Korea)
- WEEE/RoHS
- GHS and Extended SDS

MARKETS

- Packaging, Food
- Electronics
- Auto, B&C……

RESPONSIBLE CARE® PRODUCT SAFETY CODE

RC® PRODUCT SAFETY CODE JOURNEY

Historic Approach

Emphasis on managing risk

Work with customers/suppliers

Conceptual requirements in generic management system

New Product Safety Code

Safe for intended purposes

Lifecycle orientation

Transparency across Value Chain

Continuous improvement

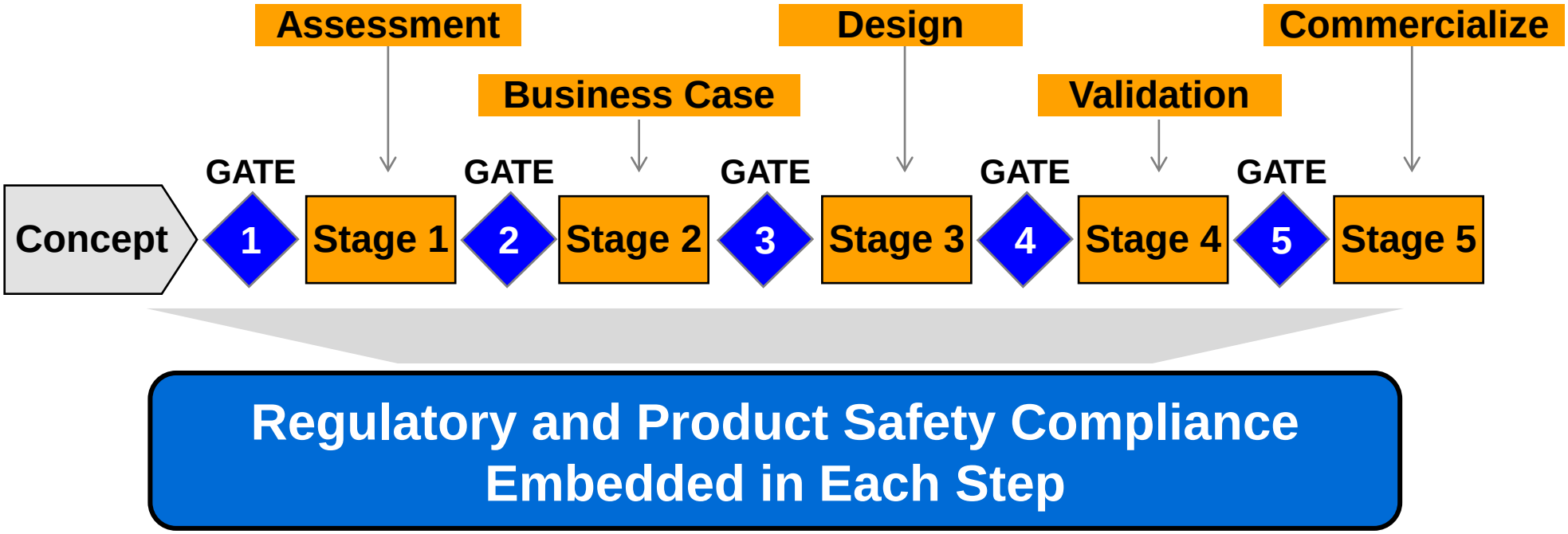
Certification Requires Mandatory Code Implementation

Enabling manufacturers to systematically evaluate, demonstrate and continuously improve product safety

MATERIAL SUBSTITUTION

- **Internal or External Drivers**
- **Alternative Identification**
- **Evaluate solutions against relevant factors**
  - Supply chain implications
  - Freedom to practice,
  - Manufacturability and cost,
  - Safety across the value chain,
  - Equivalent or superior functional performance
- **Follow Management of Change Process or New Product Design Gating Process**
- **Recent Examples…**
  - Halogen Flame retardants
  - Additives, catalysts
  - Colorants

NEW PRODUCTS



- Stages 1-2: Identify Potential Product Safety Concerns
- Stage 3: Design to Reduce Hazards and Risks
- Stage 4: Review Any Unresolved Risks
  Product Stewardship Approval to Proceed

PRODUCTS WITH SUSTAINABILITY FEATURES

Products with Proposed Sustainability Features Subjected to **Sustainability Product Safety Assessment (PSA) Tool**

Risk Assessment as Function of Hazard and Exposure

Summary	Ingredient A	Ingredient B	Ingredient C	Ingredient D	Ingredient E	Ingredient F
Regulatory						
Human Health						
Environmental Health						
Standards						
Future Risk						

EXISTING PRODUCTS

- **Sustainability PSA tool applied to existing products from:**
  - Chemical Business (100%)
  - Performance Chemicals Business (100%)
  - Fertilizer Business (100%)
  - Metals Business (100%)
- **Formulator Businesses, Polymers and Innovative Plastics, on a priority basis**
- **Ongoing fundamental chemical investigations into toxicity and other safety hazards**

PRODUCT SAFETY ASSURANCE PLANS

- **Promote Responsible Care Product Safety Code**
- **Endorse Chemical Safety Improvement Act**
- **Engage in other Association Initiatives around Product Safety**
  - **WBCSD Vision 2020**
  - **Sustainability Consortium Product KPIs**
  - **Global Eco-labels**
- **Formalize Business Metrics for application of PSA tool**
- **Remain responsive to Stakeholder expectations**

THANK YOU

RIYADH, SAUDI ARABIA

GLOBAL R&D

ALTERNATIVE ASSESSMENTS FOR PERSONAL CARE PRODUCTS

Dr. Jack Linard
Head, Regulatory Affairs Personal Care NA Unilever

FMI/GMA Sustainability Summit
Seattle, Washington

Agenda

- **Introduction**
- **Federal Regulations of Personal Care Products**
- **State Product & Chemical Regulations**
  - Green Chemistry Initiative in California
  - Proposition 65
  - Volatile Organic Content
- **Alternative Assessments: Formulating “Safer” Products**

Starting point for Building Consumer Confidence lies with all of us……

The Discussion Must Change…

From "Chemophobia"

To Confidence in Chemicals

Safety

Safety – integral part of Innovation process

Quality

Regulatory/ Legal Compliance

Communication

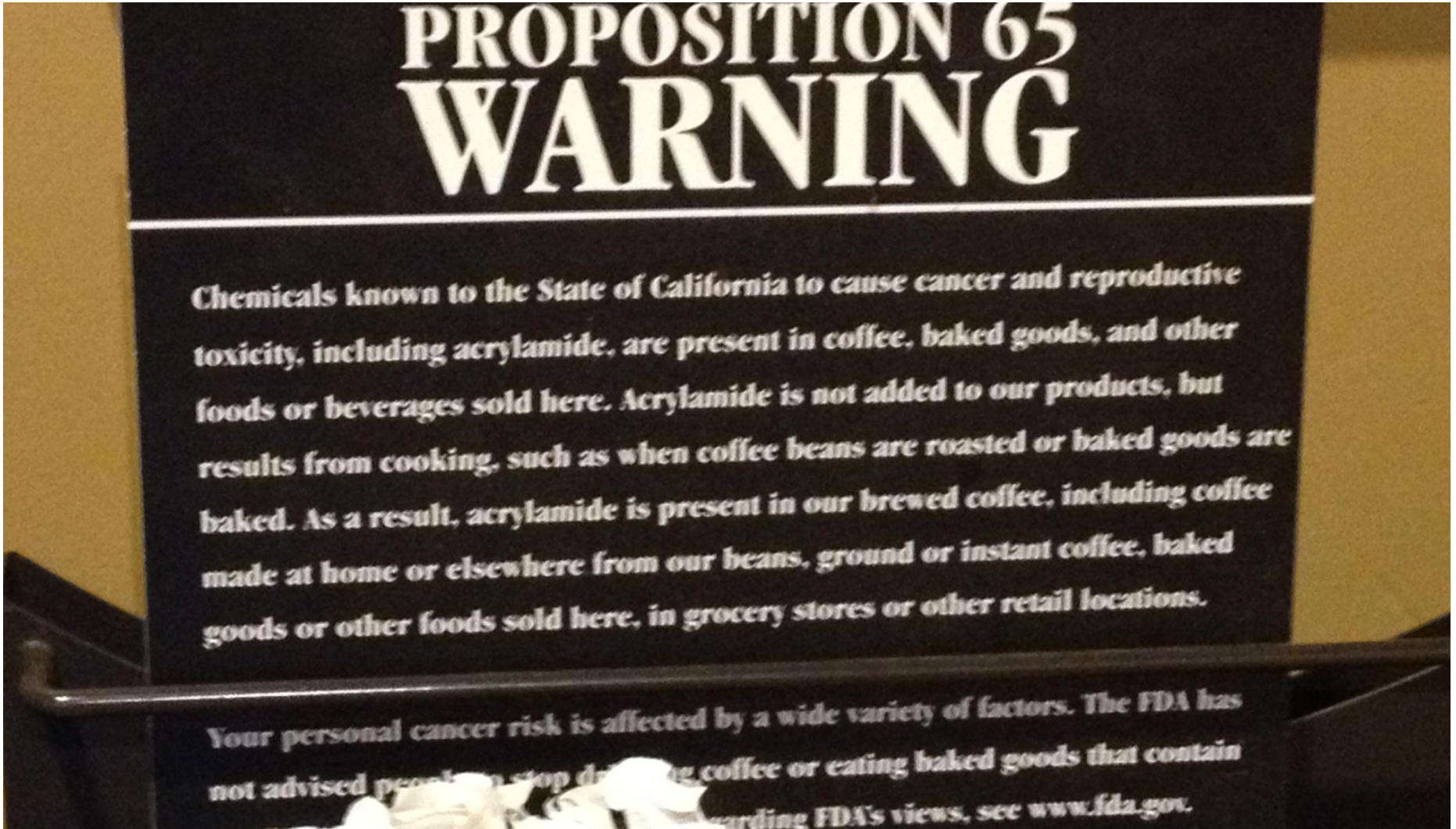
On pack, leaflets, 800 #, Websites, Facebook, Etc.

Federal Regulations

- **Food and Drug Administration**
  - Drugs: Center for Drug Evaluation and Research (CDER)
    - Includes Sunscreens, Antiperspirants, Dandruff Shampoos, Antibacterial Hand Cleansers
  - Cosmetics (aka Personal Care): Office of Colors and Cosmetics (OCAC)
- **Environmental Protection Agency & Consumer Product Safety Commission**
  - Regulate non-FDA consumer products (chemicals & products)
  - EPA regulates pesticide and antimicrobial products via FIFRA
- **Federal Trade Commission**
  - Regulates Advertising
  - Authored and Enforces the “Green Guides”

Proposition 65: the Safe Drinking Water and Toxic Enforcement Act of 1986

From a coffee shop in Sacramento, California, 2012



Proposition 65: the Safe Drinking Water and Toxic Enforcement Act of 1986

- **It is a Labeling/Notification Regulation**
  - "Prop 65" list contains naturally occurring and synthetic chemicals "known to the state" to cause cancer, birth defects, or other reproductive harm.
  - Businesses must provide a "clear and reasonable" warning before "knowingly and intentionally exposing anyone" to a listed chemical
- **Exemptions from the Labeling Requirement**
  - ***Exposures caused by the products are so low as to create no significant risk*** of cancer or birth defects or other reproductive harm (i.e., below the Safe Harbor Level)
- **"Safe Harbor Level"**
  - 300+ Chemicals have published Safe Harbor Levels
  - Businesses must determine safe harbor levels for the rest
  - **Qualified Professionals (toxicologists) are needed to fully assess if product meets the threshold criteria**

Volatile Organic Compound (VOC) Regulations

- **VOC Standards:**
  - Regulations developed by California Air Resources Board to meet U.S. EPA clean air requirements
  - Become *de facto* NA standards for VOC emissions in consumer products
  - 17 States/Municipalities have copied California standards
- **Pack Copy & Claims Determine Product Classification**
- **Examples of Standards**

Product/Category	VOC Limit
Hairspray (aerosol and non aerosol)	55%
Hair Shine (aerosol and non aerosol)	55%
Hair Mousse	6%
Hair Styling Gel	6%
Hair Styling Product – Aerosol or Pump	6%
Hair Styling Products – Other forms	2%
Astringents/Toners	35%
Deodorant Body spray	75%

How Does California's Safer Consumer Product Regulation Work?

Manufacturer does an "Alternative Assessment"

DTSC Adopts Regulations

DTSC Identifies Chemicals of Concern

DTSC Identifies Products of Concern

Manufacturers Perform Alternatives Assessments

DTSC Specifies Regulatory Responses

- No action
- Require additional information
- Product labeling
- Restrict use
- Prohibit use
- Limit access or exposure
- End of life management
- Provide grants
- Other

How Does Safer Consumer Product Regulation Work?

Manufacturer does an "Alternative Assessment"

Manufacturers of Consumer Products have been doing "Alternative Assessments for Years

We already have expertise in evaluating new ingredients and their impact on the products we sell

What goes into an Alternative Assessment?

- Provide grants
- Other

Alternative Assessments

- **It is something formulators do...**
  - Continuously and constantly
- **Alternative Assessments are a**
  - Key part of innovation and continuous improvement programs
  - Complex set of inter-related and coordinated activities
- **Principles are constant:**
  - Consumers expect that the product delivers promised performance and is
    - Safe to use, for humans and the environment
    - Affordable
    - Consistently of high and predictable quality
  - Product should be made, sourced, and disposed in a safe and responsible manner

Why do we assess alternative formulations?

- **Different Claims Desired**
- **“Improved” Formulation Required**
  - Cost
  - Performance Improvement Desired
  - Ingredient added/deleted
  - Processability Improvement
  - Raw Material Supply Issue
  - Packaging Change
  - New Safety Information
  - Stability
- **Regulatory Requirements**

Alternative Assessment Inputs: Product Safety Assessments

Human Health
Many toxicological endpoints are assessed

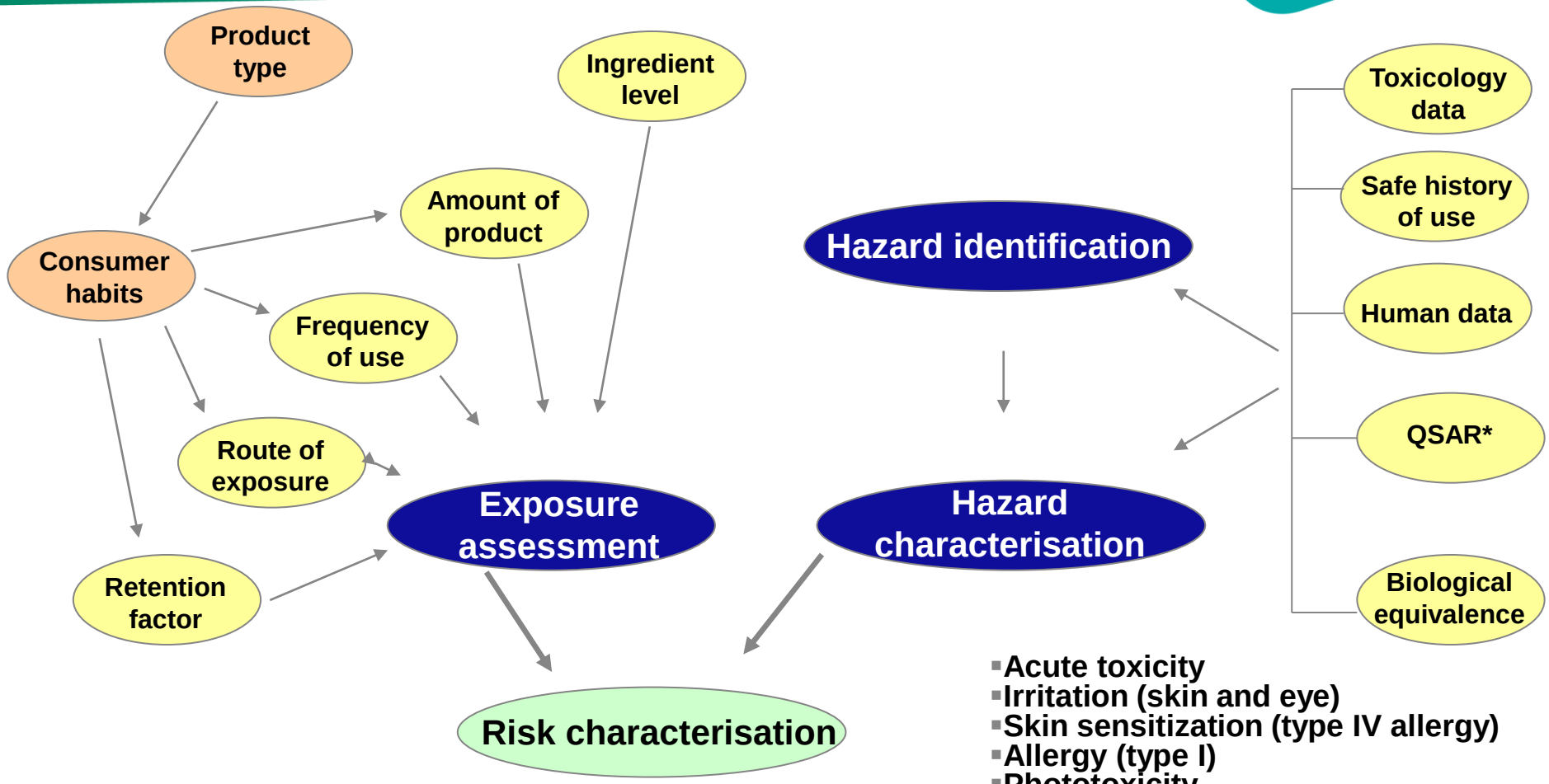
Sustainability
Environmental impact assessment - raw materials and end of life evaluation of products

Physical
Physical safety issues must be thoroughly evaluated

Occupational
Worker safety throughout supply chain is addressed

Microbiological
Product must be manufactured in a hygienic manner

Alternative Assessment Inputs: Human Health

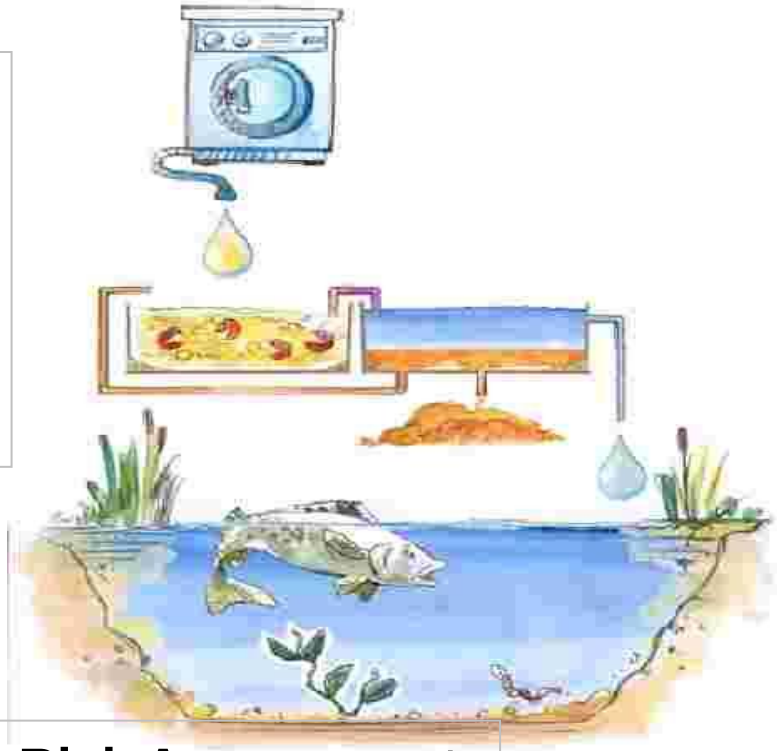


- Acute toxicity
- Irritation (skin and eye)
- Skin sensitization (type IV allergy)
- Allergy (type I)
- Phototoxicity
- Systemic toxicity
- Reproductive toxicology including teratogenicity
- Genotoxicity
- Carcinogenicity
- Inhalation toxicity

* Quantitative Structure-Activity Relationship

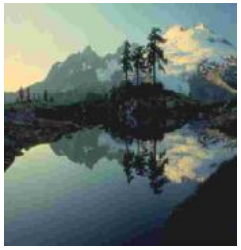
Predicted Environmental Concentration Estimation

Sewage Treatment



Terrestrial Risk Assessment

Aquatic & Sediment Risk Assessment



Environmental Toxicologists compare results to No-Effect Concentrations (**PNEC**s), with appropriate safety margins

Occupational Safety

- **Managing Hazards and Risks that arise across the Source - Make - Deliver continuum for protection of**
  - Employees
  - Members of the Public and Plant, throughout the lifecycle

- **Considerations:**
  - Ingredients
  - Formulation
  - Process Conditions
  - Equipment / Technologies
  - Packaging
  - Local Factors (e.g. scale, climate, resource / manning) etc.
  - Volume/Concentration
  - Toxicity of Raw Materials
  - Safety of Chemical Reactions

Alternative Assessment Inputs: Product Safety Assessments

- **Microbiological Safety Assessment**
  - Preservatives are meant to preserve product, not overcome poor manufacturing processes
  - Products must be made in hygienic manner
    - Good Manufacturing Principles should be utilized throughout the production and supply chain process
  - Preservation should be adequate to ensure safety throughout expected lifetime of product

- **What happens if product is not preserved adequately?**

Preservative Video.MP4

Alternative Assessments: More Considerations

Product Life Cycle

Sourcing ("natural:, mined, Synthetic)

Manufacture

Consumer use

Disposal

Breakdown Products

For each of these areas, consideration given to

- -Waste Generated
  - -Chemical
  - -Greenhouse Gases (energy to make, ship, etc.)
  - -VOC's
  - -Microbiological
- -Hazards of Waste Generated
- -Yield (higher yields are better)
- -Impurities: Generated or Naturally Occurring

Once these factors are understood….

- **Formulation Work can now begin, using candidate alternatives**
  - Alternative Formulations Prepared at Laboratory Scale
    - Evaluate Short and Long Term Physical Stability
    - Determine Cost Parameters against Current
    - Evaluate Performance in side by side comparisons
    - Modify Formulations as needed to minimize deficiencies
  - “Manufacturability”: Can your factory make it?
    - Once candidate is chosen, test in main plant trials
    - Shipping Testing
- **Patent Infringement Search**
  - Write New Patent Applications if warranted
- **Packaging Professional**
  - Designs and Tests Packages for Product
  - Molds are developed for winning designs
- **Ensure Compliance with Pertinent Regulations**

Additional Requirements and Considerations

- **Consumer Evaluation of Prototypes**
  - Do consumers see a difference?
  - Will they pay any price differential?
- **Determination of Advertising Claims**
  - Can same claims be made as for current product?
  - Can new claims be made?
- **Social & Economic Impact of Making & Using Product**
- **Biodiversity**
  - Sustainable sourcing is important
  - UN Convention on Biological Diversity

Final Thoughts

- **Alternative Analyses**
  - For the best AA to be conducted, formulators must do what they do best
    - **Develop better, innovative products for consumers & the environment**
      - **All** facets of product safety are considered
      - Green Chemistry Tenets **are** used consistently
  - Significant knowledge of many disciplines is required to perform a robust, scientifically-based alternative assessment
  - When assessing product safety
    - **a holistic and risk-based evaluation, including sourcing, use, and disposal factors, is the best way to evaluate the overall safety of that product**
    - Formulators use knowledge of the entire life cycle to determine the “best” answers
- **Goal is always to provide consumers a product that safely delivers the promised value**