



Development & Use of High Production Volume Chemical Hazard & Exposure Data in a Global Consumer Products Company



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Outline of This Talk

- Brief overview of P&G safety history and policies
- Roles that an international Consumer Product Company plays in global HPV programs and how does P&G do it
- Communication and needs for transparency and technical rigor
- Some parting thoughts



P&G Product Safety Policy

“The Company’s products and packages will be safe for consumers and the environment when used as intended.”

P&G Worldwide Business Conduct Manual

This is a business “must do” – consumers expect this commitment when buying products

The P&G logo, consisting of the letters 'P' and 'G' in a stylized, blue, italicized font.

Roles of a Consumer Product Company in HPV Programs

P&G is a Global producer of consumer goods spanning beauty care, laundry and surface cleaning products and implements, feminine hygiene, baby care, pharmaceuticals, personal care, foods and consumer electronics

300 brands

22 billion dollar brands

140 countries

3 billion consumers



P&G Safety and History

- Product safety as a function was formally established in 1971
 - previously held as part of the Product Development groups in each business
 - Response to growing concerns and science
 - Phosphate
 - NTA (nitrilotriacetic acid, a builder replacement for phosphate)
 - Non-biodegradable synthetic detergents (ABS)
 - Newly established disciplines of aquatic toxicology and the complexity of human safety
 - Established to work in parallel with Product Development



Consumer Product Companies learned early on....

- to work in consortia (LAS replacement of ABS in 1965)
- to work with academic thought leaders (new methods, technologies, rapidly evolving environment of regulations)
- to work with regulators (APHA, WPCF, formation of USEPA and needs for standard assessment approaches)
- to work with national and international standard and method setting organizations



Source of ideas, methods, and processes

Journal of the American Oil Chemists' Society (JAOCS)
Published by AOCS Press



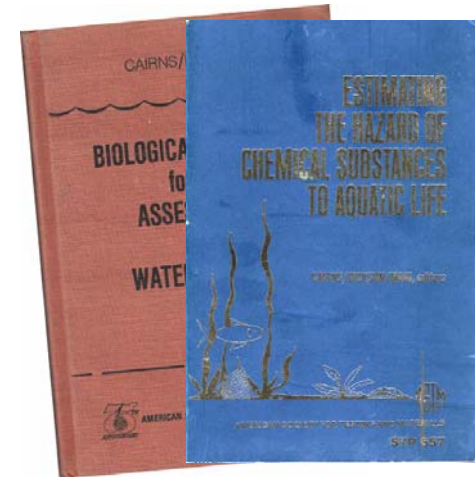
Sturm 1973. JAOCS 50:159
P&G scientists establish the method for the ready biodegradability test which is later adopted by OECD

Payne and Hall. 1978.
Internat. Verein. Theoret.
Angew. Limnol. 21:507
Algal assays developed
by these P&G scientists
were used to understand
eutrophication potential
and then modified to
assess chemical toxicity.

P&G



Cairns, Dickson,
Maki. 1978-80. A
series of workshops
and position
statements as
industry (initially
proposed by P&G),
government and
academics come to
grips with TSCA,
CWA and needs for
collaboration



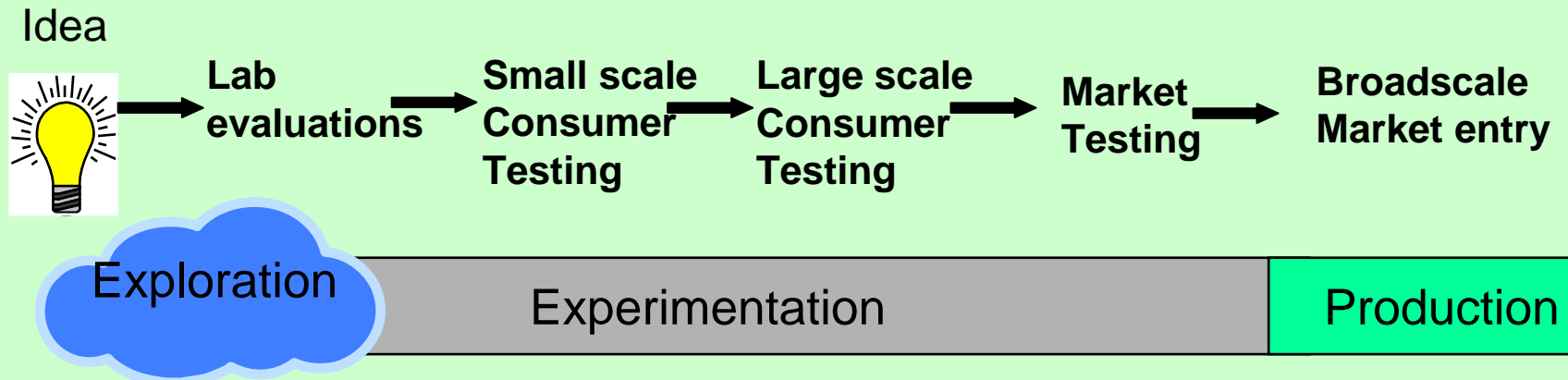
Roles of a Global Consumer Product Company in an HPV World

- Developer of data on new and existing chemicals....innovation is the lifeblood of the Company
- User of HPV data in decision-making
- Communicator of HPV data
- Participant in key research fora, trade associations, and HPV consortia

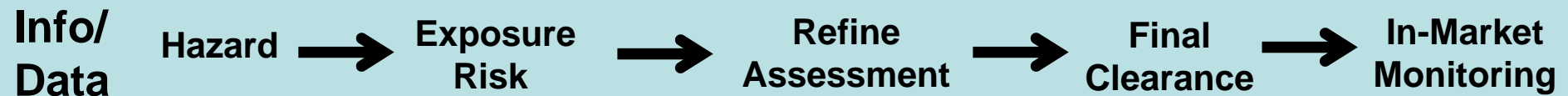


Safety Designed In—*Right from the Start*

Product Development



Safety Evaluation



> 200 Human and Environmental Safety Scientists

Every Ingredient, Every Package, Every Product

The Reality for How Industry Uses HPV Assessments

- *Risk assessment as an operating paradigm is based on the principle that a chemical is not safe or unsafe; however, it's the use and exposure of a chemical that can be judged as safe or unsafe*
- *To do this requires fundamental knowledge of exposure, habits and practices, and intended uses*



Developer of HPV data

- Method development for Company and industry wide use
 - New biodeg methods for less studied compartments
 - Methods for ED screens using fish
 - Animal alternatives
- Specific test programs, facilities, and research to support critical HPV needs
 - Maintenance of internal expertise to rapidly support development of upstream chemicals (allergenicity, mutagenicity, sensitization)
 - Experimental Stream Facility







Experimental stream mesocosm – a simulation of complex environmental interactions and resident species exposed to chemicals over the time frame of months. The primary objective is to understand the extrapolation of single species data to the ecosystem.

This test system drove the final effects interpretation for the LAS (anionic surfactant) HPV environmental effects (hazard) submission in 2002.

A system such as this provides immediate integration of both exposure and hazard

As a Developer of Safety Data...

- Commitment to methods development for exposure and hazard understanding because risk assessment is always an evolving science
- Use of a tiered risk assessment process is essential to prioritizing needs for data
- Significant involvement with new to the world chemistry (PMN substances), when these are successful they become HPVs!

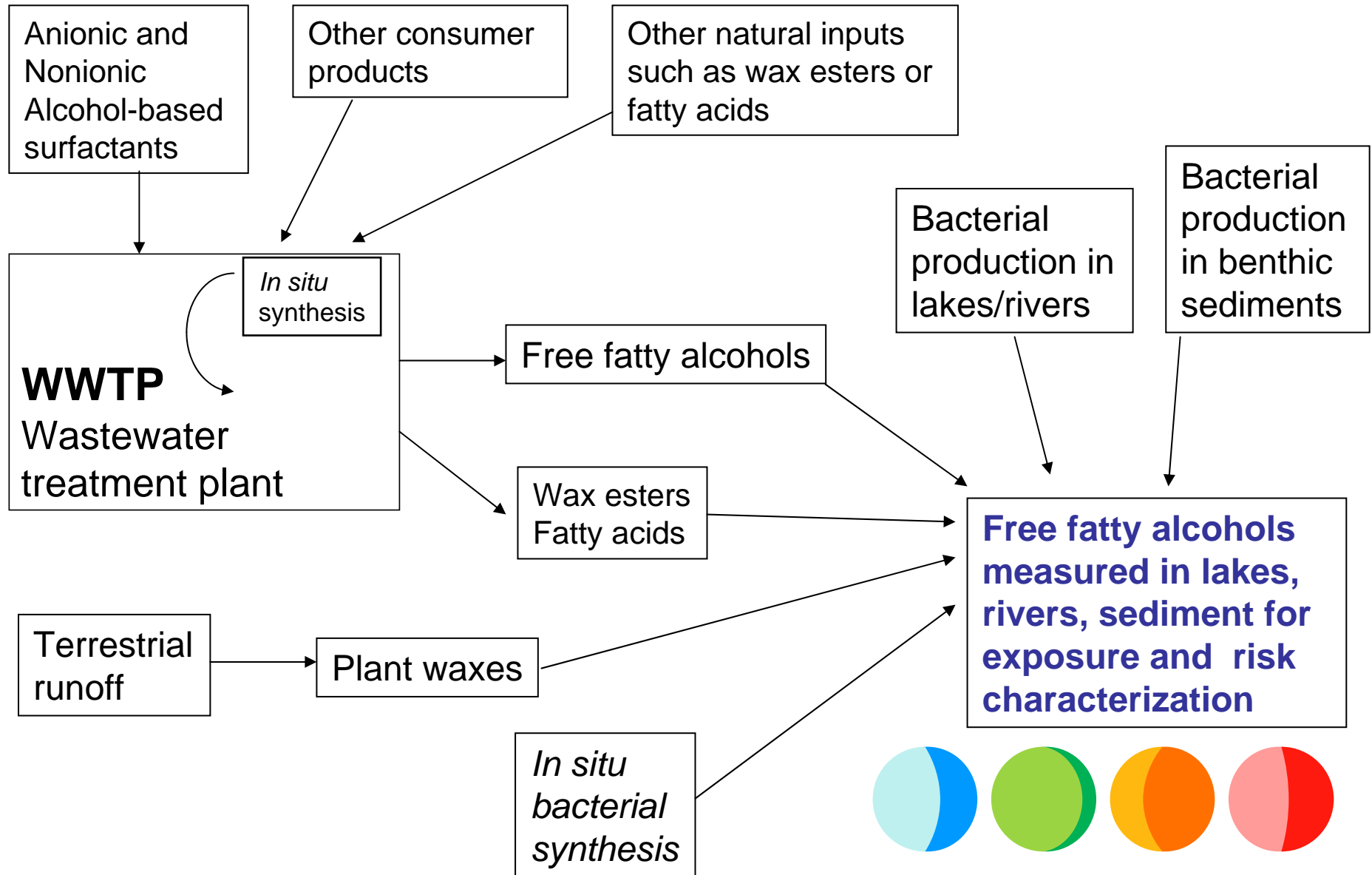


User of HPV Data

- HPV risk assessments must consider industry wide uses, volumes and exposure
 - The entire process forces (in a good way) discussion of data quality and abundance by submitters
 - Identifies data gaps and how they might be resolved (e.g., the Aliphatic alcohols HPV submission)



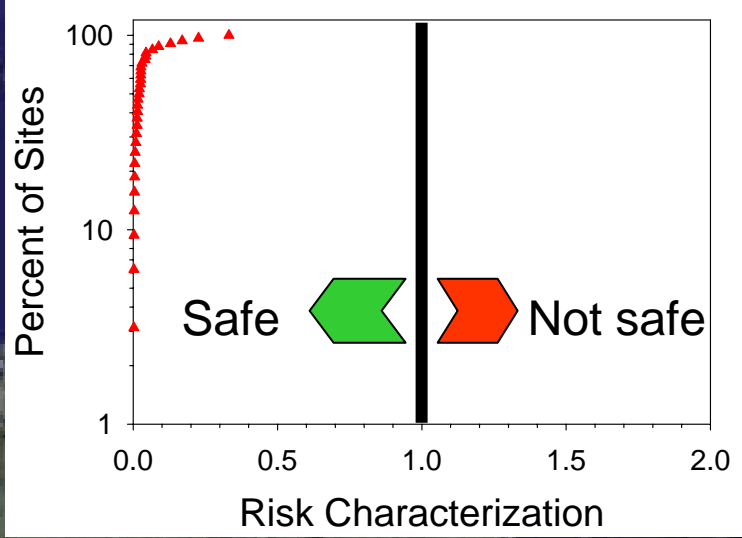
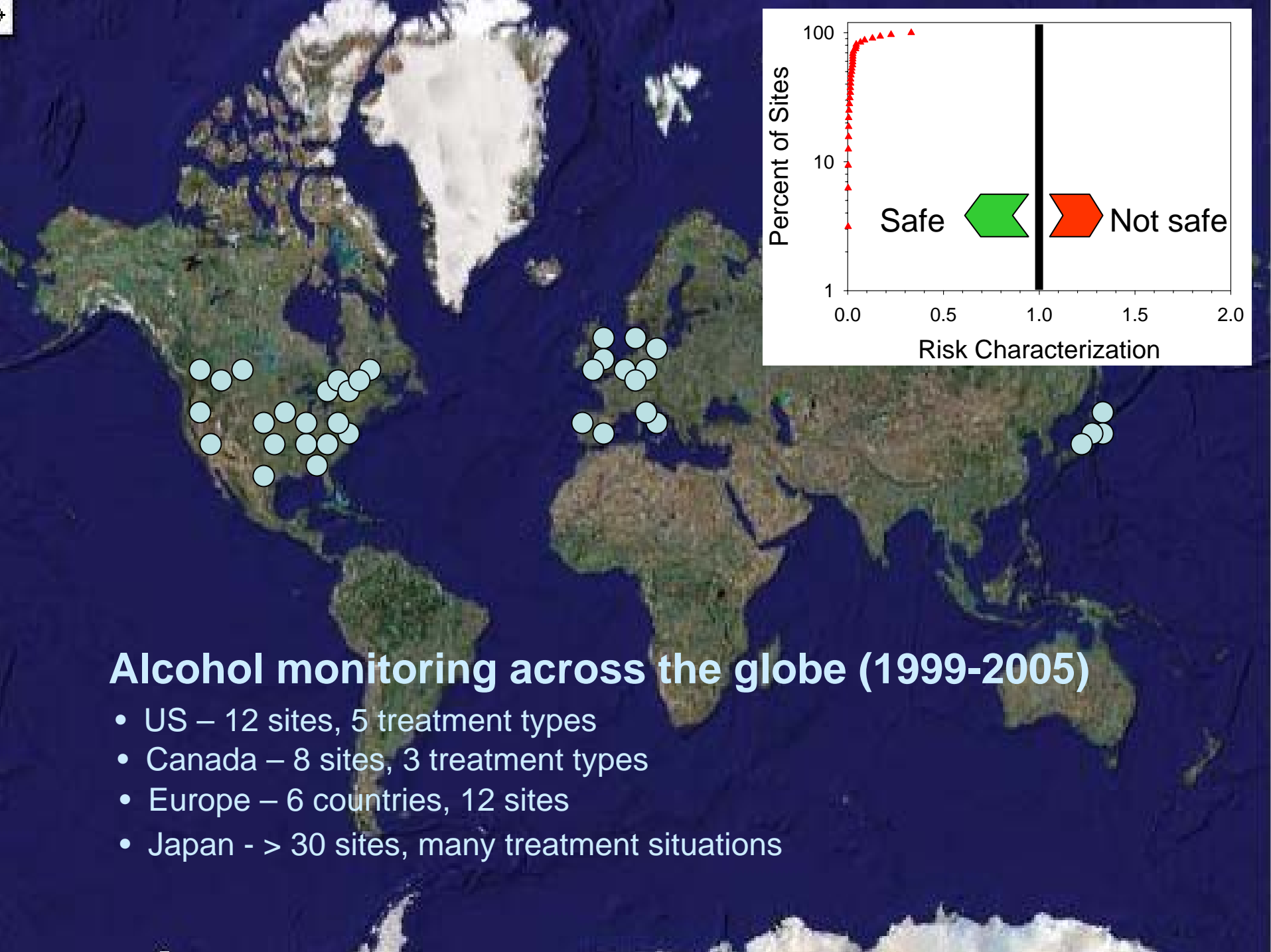
Sources of Alcohol in the Environment





Alcohol monitoring across the globe (1999-2005)

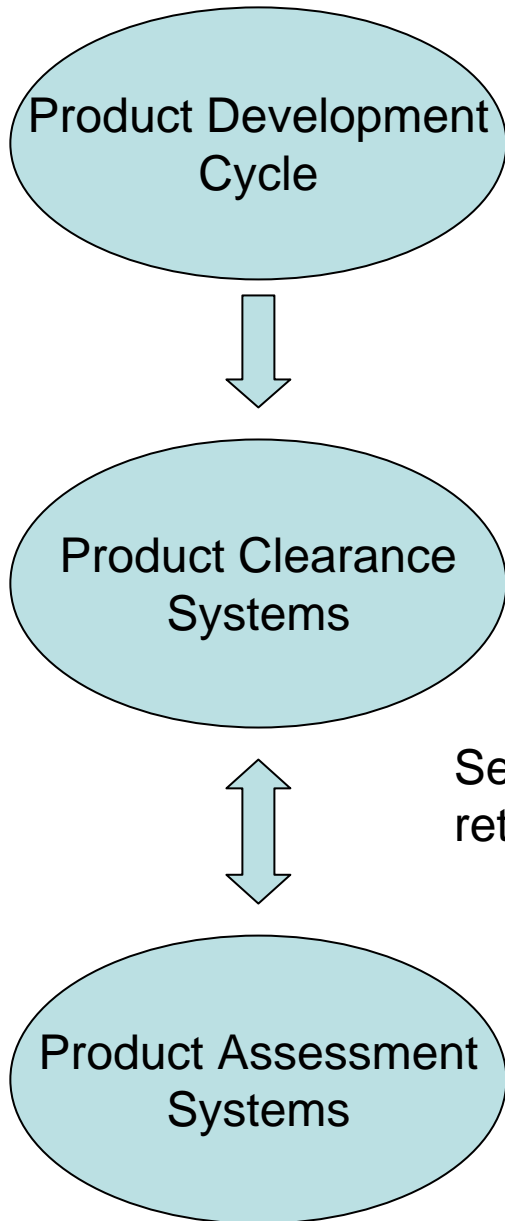
- US – 12 sites, 5 treatment types
- Canada – 8 sites, 3 treatment types
- Europe – 6 countries, 12 sites
- Japan - > 30 sites, many treatment situations



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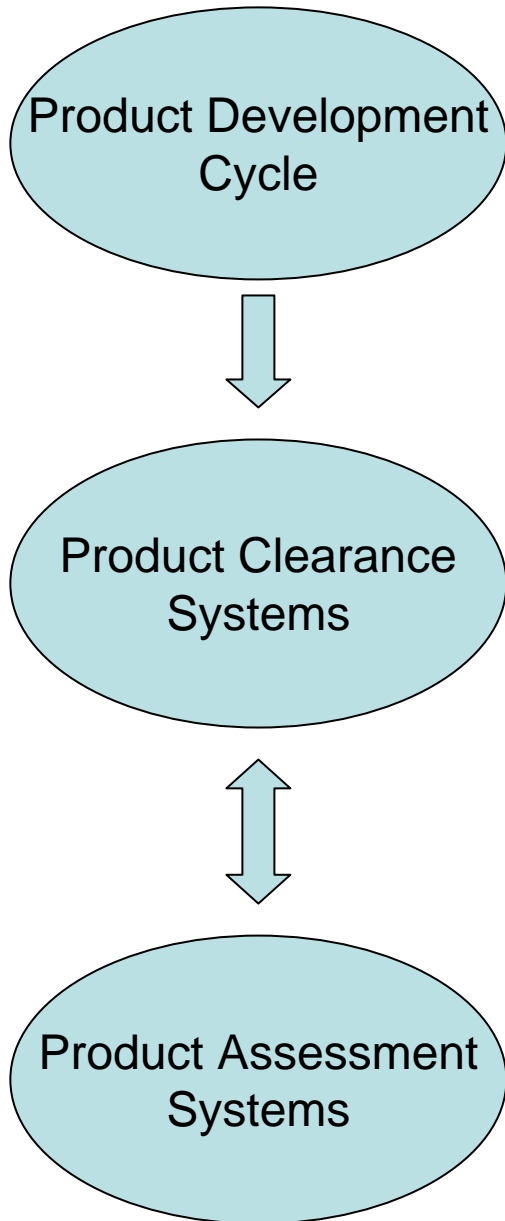
User of HPV Data



Search for and retrieve data

The screenshot shows the **BIS/TS Chemical Hazard Search Strategy** web interface. It features a search bar at the top and a navigation menu with buttons for **Search IM**, **Search CT**, and **Product Assessment GPSDS**. The main content area is titled **Stage 1 PS&RA Assessment Strategy** and includes a detailed list of databases searched, such as OECD, EPA, and various international agencies. It also provides search options like **Search GRASP**, **Internal Search**, **External Search**, and **Search CTFA On-line**. A black arrow points from the text 'Search for and retrieve data' to the **External Search** section. At the bottom, there is a link to **Click here to Create a Chemical Hazard System Request**.

User of HPV Data



InnovationNet Search Inet Tools Inet Help myPG.com

PS&RA | CPS | Clin | Env | HS | Micro | Reg | ER Contact: _____

Home | PS&RA Community | HS Expert Teams | **P&G Ingredient Info & Risk Assessment Center** | Training Center | Internal & External Links

P&G Ingredient Info / Risk Assessment Center

P&G Ingredient Information (PS&RA specific)	Exposure Assessment	Current Best Approaches (CBAs)
<ul style="list-style-type: none">Ingredient PagesChemical Hazard SystemInstitutional Memory (Ref. Lib, CT, WTDS, etc.)CCETWTDSPA - TNG (New - try it, you'll like it!!!)WebPA (training schedule for Web PA)ThesaurusPublicationsPresentationsBeauty CareF&HCStudy Managementsecurity form to obtain access to PS&RA data systems (IMPACT)VSD Calculations <p>Other Sources of P&G Ingredient Information</p> <ul style="list-style-type: none">Technical Reports	<ul style="list-style-type: none">Exposure Assessment PrinciplesCBA's for ExposureHabits and PracticesConsumer Products Exposure ModelInhalation Exposure ModelWELLA ModelsRegulatory Exposure ModelsProbabilistic and Probabilistic-Aggregate Exposure Model <p>Chemical Identification</p> <ul style="list-style-type: none">Institutional Memory's ThesaurusARIELCASChemFinderChemDplusCRCCTFA HandbookExichemGINCGlossary Organic ChemLogKOWMerk IndexMSDS for Infectious Substances -Health CanadaPRTRs	<ul style="list-style-type: none">Risk Assessment CBA <p>Other RA Docs of interest:</p> <ul style="list-style-type: none">Threshold of Toxicologic Concern (TTC)Previous TTC doc for historical perspectiveRelative vs. Absolute Systemic AbsorptionDose Conversions and Default ExtrapolationsSlides used in 21 June 2004 Review with the External Advisory Board (EAB)Acute ToxicityCancer Risk AssessmentDermal IrritationDermal PenetrationDermal SensitizationDraft P&G CBA for Enzyme RAsDraft SDA Consumer RAEye IrritationGenotoxicityMucosal IrritationNeurotoxicology

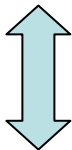
Web-based systems for use by human and environmental safety scientists to standardize and drive state of the science assessments

User of HPV Data

Product Development Cycle



Product Clearance Systems



Product Assessment Systems

Human exposure Calculation - Beauty Care GBU
Version: 10/2/06 10:27

Name: _____
Date: 12/4/06 2:05 PM

Category: Personal Cleansing
Skin Care

Product(s): Facial Moisturizer Cream/Lotion - with UV
Facial Moisturizer Cream/Lotion - without UV
Facial Treatment Serum
Hand Cream
Lotion/Body Cream
Lotion/Body Sun Cream (beach/sport)

Link to Product CBA: [CBA_Web_Site](#)

Habits and Practices spreadsheet data to be used: Default Regional Selected: Global Def: 9/28/06 14:14

Human factors spreadsheet data to be used: Default Regional Selected: Female, D: 9/28/06 14:13

Ingredient or Component name: _____

Concentration of Ingredient in product (Cpi) _____ %

Concentration of Component in Ingredient (Cpc) _____ %

Concentration of Ingredient or Component of Interest (Cp) 0 % Cp = Cpi*Cpc

Exposure Scenario: Product on skin due to product use

Dermal exposure - Systemic

Parameter and Description	Units	Reference	Comment
Cp	Ingredient/contaminant conc. in product	0.000000 %	
Ap	Application of product	4.5000 g/use	3
F	Frequency of use	2.000 uses/day	3, 6
ApF	Product use per day	0.000 g/day	ApF = Ap*F
D	Dilution	100.00 %	
Rs	Percent product remaining on skin	100 %	23
Ab	Absorption of material	100 %	

Buttons: Save Draft, Load Draft, Exposure Report, Calculate MOE

Ready NUM

Including exposure models for every product, category and use type

User of HPV Data

- Scientists recognize the complex data and evaluations (internal use, external use, regulatory, stakeholder expectations, etc.)

- In addition to the internal systems we use as in the previous slide...

- We invest in developing new decision support systems for use by others outside the Company (AMBIT, CEFIC LRI project taken over by OECD)



The screenshot shows a web browser window titled "AMBIT project - Microsoft Internet Explorer". The address bar shows "http://ambit.acad.bg/". The page content includes a blue header with the text "Codename AMBIT: Building blocks for a future (Q)SAR decision support system". Below the header is a navigation menu with links for "About", "Search", "database", "Download", and "Documentation". The main content area features the text "CEFIC LRI EEM-9" and "Building blocks for a future (Q)SAR decision support system : databases, applicability domain, similarity assessment and structure conversions (codename AMBIT)". A link for "AMBIT database Online" is provided, along with the names "Nina Jellazkova and Joanna Jaworska". The "Project description" section begins with "AMBIT, a software for chemoinformatic data management, is an outcome of the LRI project: 'Building blocks for a future (Q)SAR ((Quantitative) Structure Activity Relationship) decision support system'." and continues with details about the software's purpose and availability.

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1,2-Ethanediamine

[find similar compounds](#)

Synonyms: ,ETHYLENEDIAMINE
CAS number: 107-15-3 18299-54-2 333-18-6
SMILES: NCCN
Molecular Formula: C2H8N2
Molecular Weight: 60.069
[Acoustic toxicity data from AQUIRE database](#)

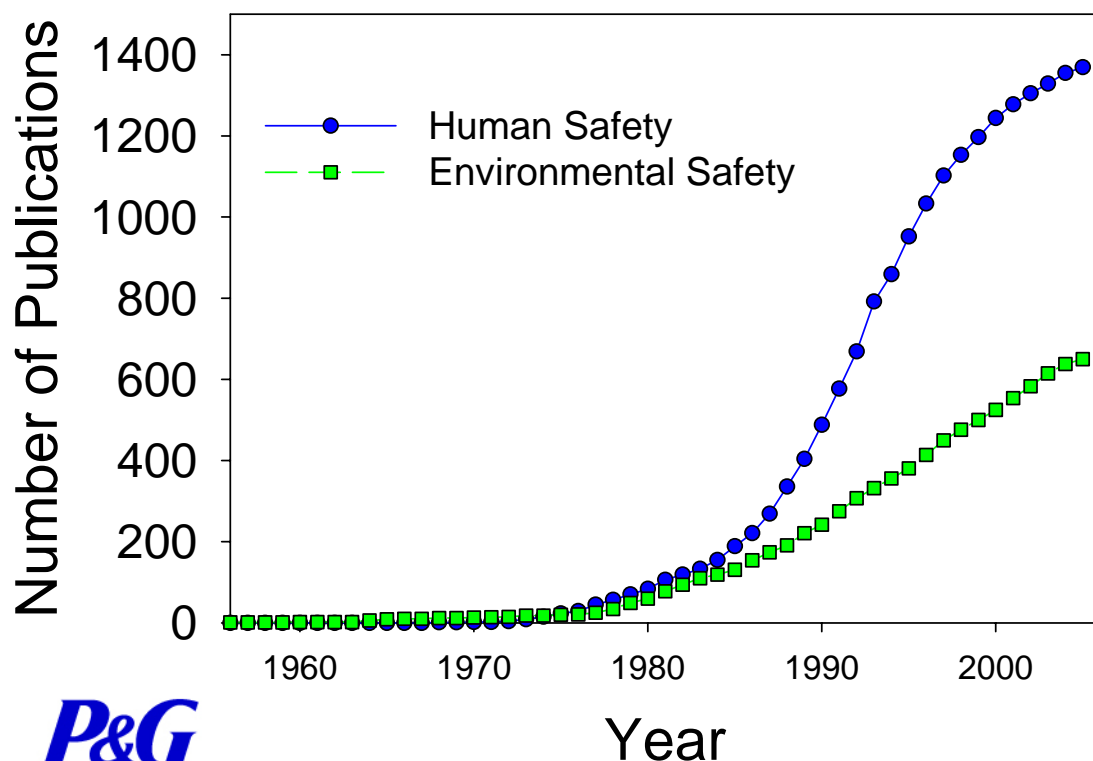
[3D picture](#)

Found in following datasets:	Identifier	Value
249071 3D NCI structures	NSC	16396
249071 3D NCI structures	NSC	26349
KOWWIN validation set	ChemName_IUPAC	ethane
EPAFHM v2a 617 1Mar05.scf	ChemName_IUPAC	ethane
KOWWIN validation set	INChI	INChI=1-2-4-
EPAFHM v2a 617 1Mar05.scf	INChI	INChI=1.12Beta/C2H8N2/c3-

Data for ~500,000 chemicals embedded

Communicator of HPV Assessments and Related Works

- Technical transparency...through presentations and publications



Data excludes the pharmaceutical business

Since 1975:

- 43 publications/yr for HS
- 21 publications/yr for ES

Presentations = 10X publ.

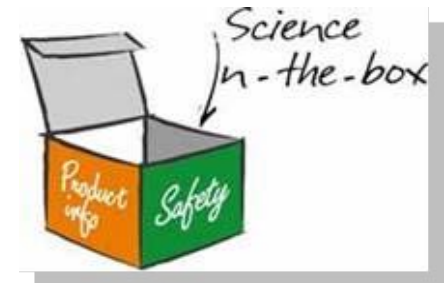


Communication – Through Websites

- **Science in the Box**

- Laundry and cleaning products
- 25,000 visitors/month
- Access to safety, MSDS, other info

www.scienceinthebox.com



- **Science of Beauty**

- Pilot launched 12/04
- Pantene, Olay
- Working to add additional brands

www.pgbeautyscience.com



- **P&G Perspectives**

- Editorial views on product safety, policy issues
- Target audiences: authorities, scientists, other influencers

www.pgperspectives.com



How do we do this? Collaboration



Work with suppliers, competitors and retailers via trade associations and in technical organizations

- Share best safety practices
- Develop/share risk assessments
- Work with stakeholders
- Engage in local, regional and global chemical policy discussions



Every Chemical is a Potential HPV

- Embedded in our technology screening process (what if this is a winning chemical solution to address a consumer need...?)
- Exposure-based risk assessment is the driving force; by risk-based selection of fate or hazard properties we can bring the principles of green chemistry to life
 - LAS vs ABS (1960's)
 - alcohol ethoxylate vs alkyl phenol ethoxylate (1970's)
 - DEEDMAC ester-linked softeners versus DTDMAC (1980-90's)
 - EDDS chelators versus EDTA (1990's)
- It starts with risk and extends to structural screening/alerts and sustainability tools



Summary

- P&G as a Global Consumer Product Company has several roles to play:
 - Builder of appropriate tools/methods
 - Developer of HPV data
 - User of HPV data
 - Communicator of assessments
 - Active contributor and leader in 10 HPV consortia covering ~400 CASNos
- Exposure and risk are fundamental to decision-making and meeting Company safety policy

