Dear GRSP members:

I have attached the staff presentations for our meeting this week. They are listed here in the order of the agenda.

1. Overview
2. Chemicals of concern / priorities
3. Clearinghouse Hazard Traits
4. Alternatives analysis

Please note that we will have copies of all materials prepared for you. Also, all meeting materials are posted on our website, here:
http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/index.cfm

I have included two additional documents:

5. GRSP member Dr. Lauren Heine forwarded this document that may be of interest: "Growing the Green Economy Through Green Chemistry and Design for the Environment."
6. Californians for a Healthy and Green Economy (CHANGE) recently submitted to DTSC a letter in which the Green Ribbon Science Panel was copied. As a courtesy to CHANGE we are sending you a copy of that letter.

Thank you and we're looking forward to meeting you all in a few days.

California Green Chemistry Program

Green Ribbon Science Panel
Agenda Item #3

April 29, 2009

Donald Owen, Jr., P.E.
Department of Toxic Substances Control
California Environmental Protection Agency

OVERVIEW

- *Final Report*
- *Two New Statutes*
- *Brainstorming*
- *Draft Straw Rule*
- *Questions for the Panel*

FINAL REPORT

Six Policy Recommendations

1. Expand Pollution Prevention
2. Develop Green Chemistry Workforce, Education, Research, and Tech Transfer
3. Create Online Product Ingredient Network
4. Create Online Toxics Clearinghouse
5. Accelerate Quest for Safer Alternatives
6. Move Toward Cradle-to-cradle Economy

Green Chemistry
Two California laws

- **Chapter 559**
  (Assembly Bill 1879): develop framework for addressing chemicals of concern, evaluating alternatives, and moving toward safer consumer products

- **Chapter 560**
  (Senate Bill 509): increase information about toxicity and other "end-points" for chemicals via an online portal

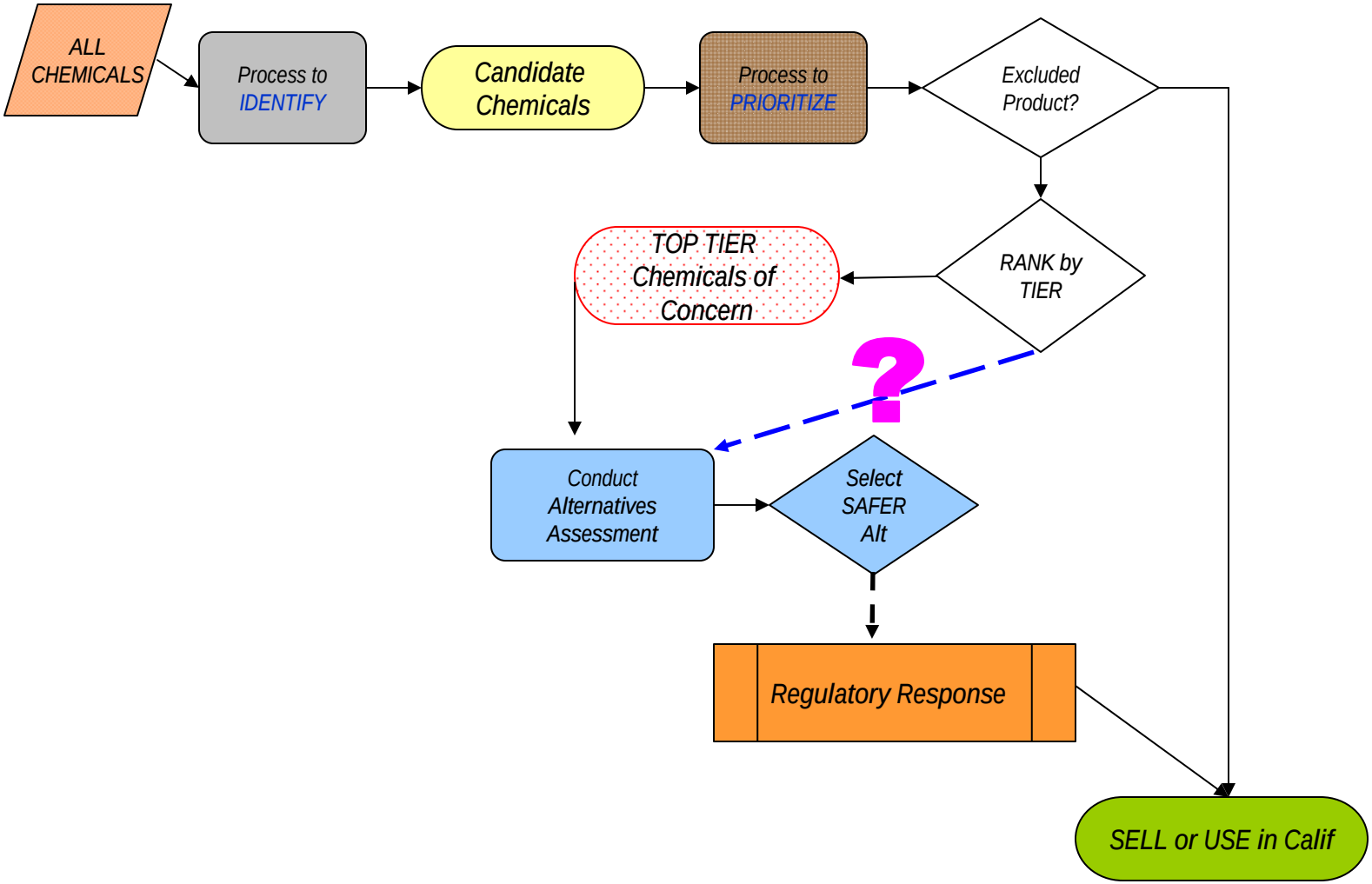
DTSC1

Brainstorming

- Wiki for Ideas for Draft Rule
- Informal Workshops
- Consultation
- Green Ribbon Panel Advice
- Formal Rulemaking

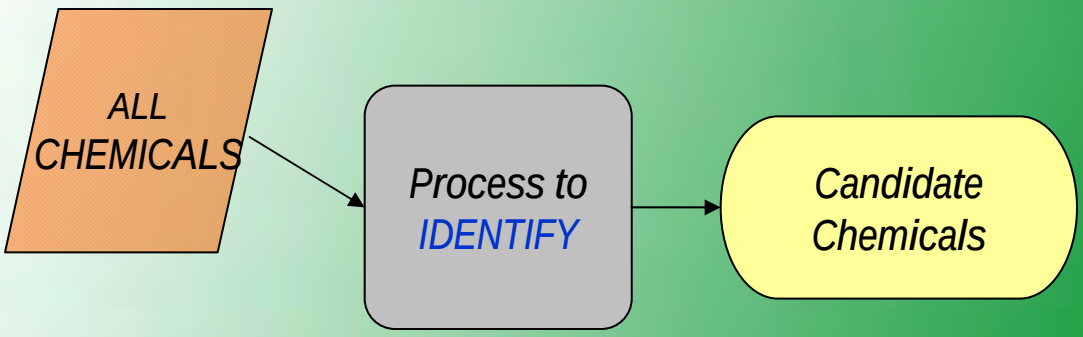
Safer Alternatives

Rough Draft Flow Concept



Safer Alternatives

Step 1: Process to Identify Chemicals

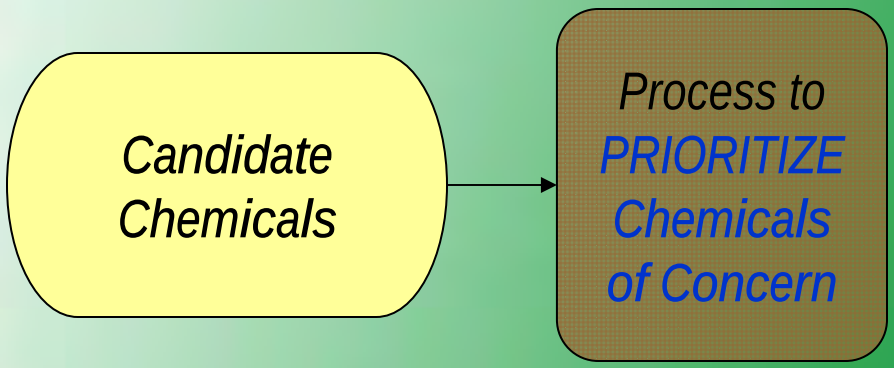


State adopts a process, which sets criteria for identification:

- Hazard end-points (CMR, PBT, etc.)
- Authoritative bodies
- Both knowns and unknowns
- Existing and new chemicals
- Use proxy methods
- Other criteria ?

Safer Alternatives

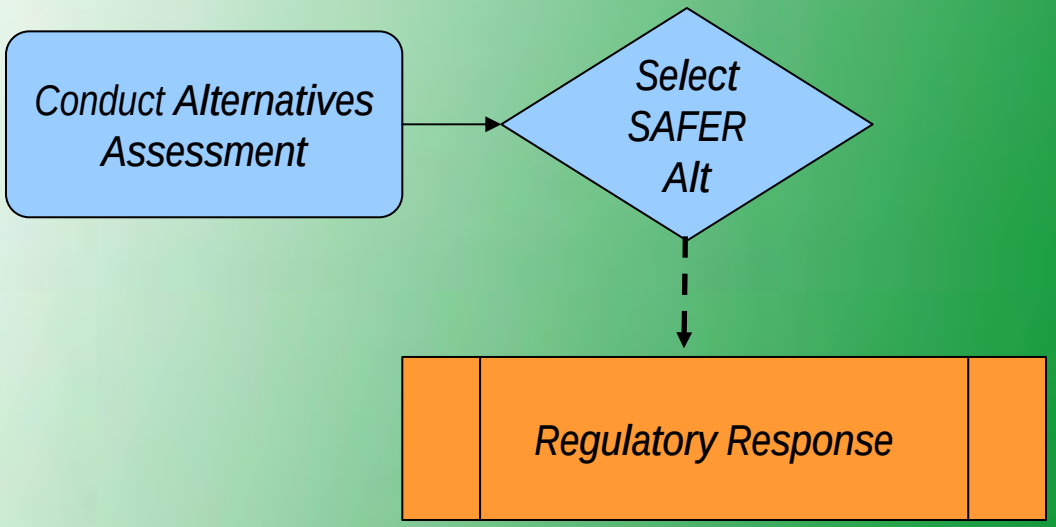
Step 2: Process to Prioritize Chemicals of Concern



State adopts a process, and sets criteria, which divides the candidate chemical universe into tiers.

Safer Alternatives

Step 3: Evaluate Alternatives Applying Lifecycle (to Product)



Manufacturer evaluates feasible alternatives using appropriate methodology/tools. Compares alternatives and generates analysis which guides selection and any necessary regulatory response(s).

Safer Alternatives

Step 4: Regulatory Response

REGULATORY RESPONSE:

- *Monitor*
- *Label*
- *Restrict or condition use*
- *Conduct research*
- *Require end-of-life management*
- *Other ?*

Which condition(s), in alternatives analysis, lead to which response(s)?

Agenda Item IV:
Chemicals of Concern/Setting Chemical Priorities

(Identification & Prioritization of Chemicals and Chemical Ingredients of Concern in Consumer Products)

Rob Brushia, Ph.D.
Research Scientist III

What does the statute say?

- The department shall adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern…
  - The regulations shall establish an identification and prioritization process that includes, but is not limited to, all of the following considerations:
    - (1) The **volume** of the chemical in commerce in this state.
    - (2) The **potential for exposure** to the chemical in a consumer product.
    - (3) **Potential effects on sensitive subpopulations**, including infants and children.

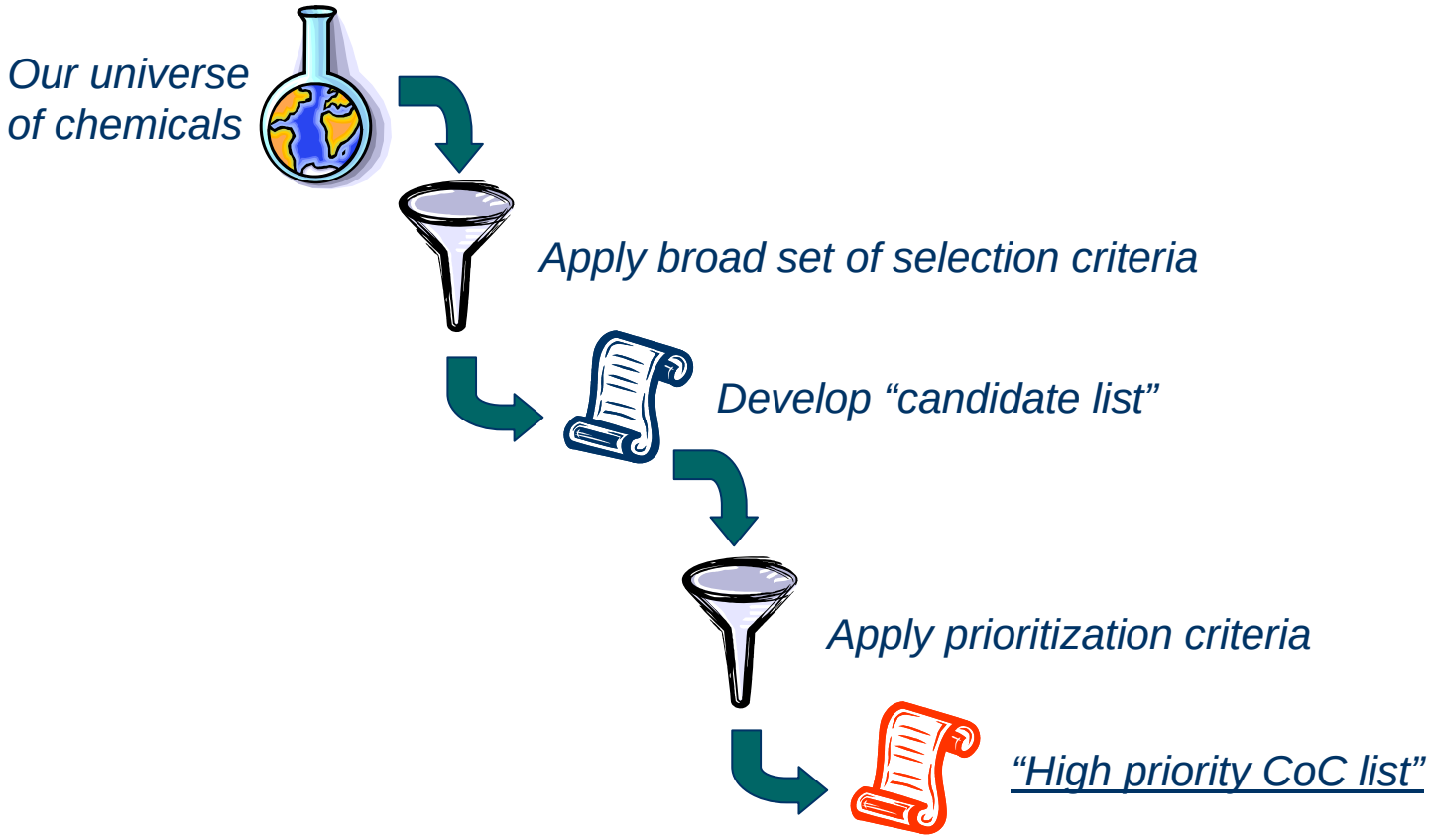
- In adopting regulations pursuant to this section, the department shall develop criteria by which chemicals and their alternatives may be evaluated.

- In adopting regulations pursuant to this section, the department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes...

Definitions

- The law does not define “chemicals” or “chemical ingredients” in consumer products. Possible definitions:
  - Chemical in a consumer product: is any chemical or substance that is not added intentionally, but ends up in a consumer product incidentally, including naturally occurring chemicals present in raw materials.
  - Chemical ingredient in a consumer product is any chemical or substance that is intentionally added to the consumer product or any part of the consumer product during any stage of the manufacturing process, and that remains in the consumer product that is offered for sale.

Identification and prioritization of chemicals of concern (CoCs), overview



Identification of CoC's

- DTSC has considered various options with respect to criteria for the candidate list, including:
  - Adopt a large set of criteria to capture a large universe of chemicals.
  - Adopt a vary narrow set of criteria (e.g., only chemicals found in cord blood) to capture a very small universe of chemicals.

Identification of CoC's

- DTSC has opted to use a large set of criteria and capture a large universe of "candidate" chemicals.
  - Any chemicals that fit one or more criteria would be placed on the "candidate list".

Criteria for inclusion on candidate list

- Possible criteria include:
  - Chemicals for which a minimum data set (e.g., SIDS data) is not available.
  - Criteria established by other California regulatory programs (e.g., proposition 65) and other authoritative bodies (e.g., EU, Canada);
  - Chemicals on lists established by other authoritative bodies);
  - Carcinogens;
  - Endocrine disruptors;
  - vPvB substances;
  - PBTs;
  - Mutagens, or reproductive mutagens or toxins;
  - And others.

Questions regarding our criteria for the “candidate list”

- Is our proposed list of criteria for inclusion on the candidate list appropriate?
  - Are there additional criteria we should consider?

Prioritization

- Once we have a candidate list, we will apply a set of “prioritization” criteria to identify and prioritize chemicals of concern.
  - We will develop a list of “high priority chemicals of concern” based on the prioritization process.

Prioritization

- Possible prioritization criteria:
  - Volume contained in consumer products; (what threshold for “high” priority?)
  - Potential for exposure; (e.g., is there expected, known, or anticipated release during use or at end of life?)
  - Exposure based on biomonitoring data;
  - Potential effects on sensitive subpopulations, including infants and children;
  - Lack of minimum data sets (e.g., the six hazard endpoints, acute toxicity, chronic toxicity, teratogenicity or developmental and reproductive toxicity, mutagenicity, ecotoxicity, and environmental fate, comprising the "Screening Information Data Set" (SIDS) test battery established by the OECD, 1998);
  - Any evidence suggesting that there are “reasonable grounds for concern” regarding the potential adverse impacts of the chemical;
  - And others.

Prioritization

- Any chemical falling into any one of our prioritization categories (or exceeding a specified volume of use or concentration threshold) would be designated a “high priority” chemical of concern.

Questions regarding prioritization

- Are our prioritization criteria appropriate?
  - Did we miss any?
- With respect to “volume”, what is the appropriate threshold to classify something as “high priority”?
  - Should concentration in a consumer product also be a consideration for prioritization?
- Should we identify chemicals as “high” or “low” priority only; or, should we establish priority “tiers”, and criteria for each tier?
    - How many tiers would be appropriate?
    - What criteria should be used for each tier?

The End

- Thank you

Toxics Information Clearinghouse Hazard Traits

Presentation to Green Ribbon Science Panel Meeting April 29-30

Sara Hoover
Office of Environmental Health Hazard Assessment

What is the Clearinghouse?

- Established by SB 509:
  - "Decentralized Web-based system for the collection, maintenance, and distribution of specific chemical hazard trait and environmental and toxicological end-point data"
  - "Accessible to the public through a single Internet Web portal"
  - DTSC shall "operate the clearinghouse at the least possible cost to the state"

Clearinghouse content

- On or before January 1, 2011, OEHHA shall:

  "…evaluate and specify the hazard traits and environmental and toxicological end-points and any other relevant data that are to be included in the clearinghouse."

- Green Chemistry Initiative Final Report recommends starting with existing data from authoritative sources:
  - California and other states
  - Federal government
  - Other nations (e.g., Canada, European Union)
- Generating new data requires a prioritization process (AB 1879)

AB 1879 link to SB 509

- DTSC shall establish a process to identify and prioritize chemicals of concern in consumer products, which will include:
  - Volume in commerce
  - Exposure potential
  - Potential effects on sensitive subpopulations

- As part of the process, DTSC shall develop criteria for evaluating chemicals and alternatives, which will include:
  - “The traits, characteristics and endpoints that are included in the clearinghouse data”

Clearinghouse development to date

- Research on existing definitions, identification/evaluation methods, and data sources for hazard traits and endpoints
- Preliminary concepts
  - Identify chemical characteristics linked to hazard
  - Include “exposure traits”
  - Build in hierarchical structure linking early indicators to toxicological/environmental endpoints
  - Include evaluation - identify known and suspected hazards

Consultation process

- Ongoing meetings between OEHHA and DTSC
  - In contact with other states and countries regarding data sharing
- OEHHA public workshop on January 29, 2009
  - Brainstorming session
  - Input on broad questions from public and expert panel
- OEHHA, UCLA, UCB jointly applied for funding for workshop series
- Formal consultation with other state agencies planned

Jan 29 workshop on Clearinghouse

- Expert panel with members from:
  - Academia
  - Federal government
  - Industry
  - Nongovernmental organizations
- Included some members now on Green Ribbon Science Panel
- Wide range of stakeholders participated

Jan 29 workshop questions

- What characteristics should be considered a “hazard trait”?
- What hazard traits and toxicological/environmental endpoints should be included in Clearinghouse?
- What traits/endpoints/other data would be useful in identifying a chemical of concern without a full toxicological database?
- What traits/endpoints/other data would be useful in evaluating exposure potential?
- What traits/endpoints/other data would be useful in evaluating effects on sensitive subpopulations?

Jan 29 workshop highlights

- Cast broad net for “hazard traits” and chemicals
  - Prioritize hazard traits to consider first
  - Don’t just focus on data-rich chemicals, bad actors
- Incorporate emerging, “upstream endpoints”
  - E.g., endocrine disruption
  - Don’t extend too far into less well understood endpoints
- Don’t neglect traditional endpoints
  - Various lists of endpoints suggested
  - Include ecotoxicity - go beyond aquatic receptors
- Include physical chemical properties
- Use computational toxicology, structural alerts
- Include same set of hazard traits for all chemicals

Jan 29 workshop highlights, cont.

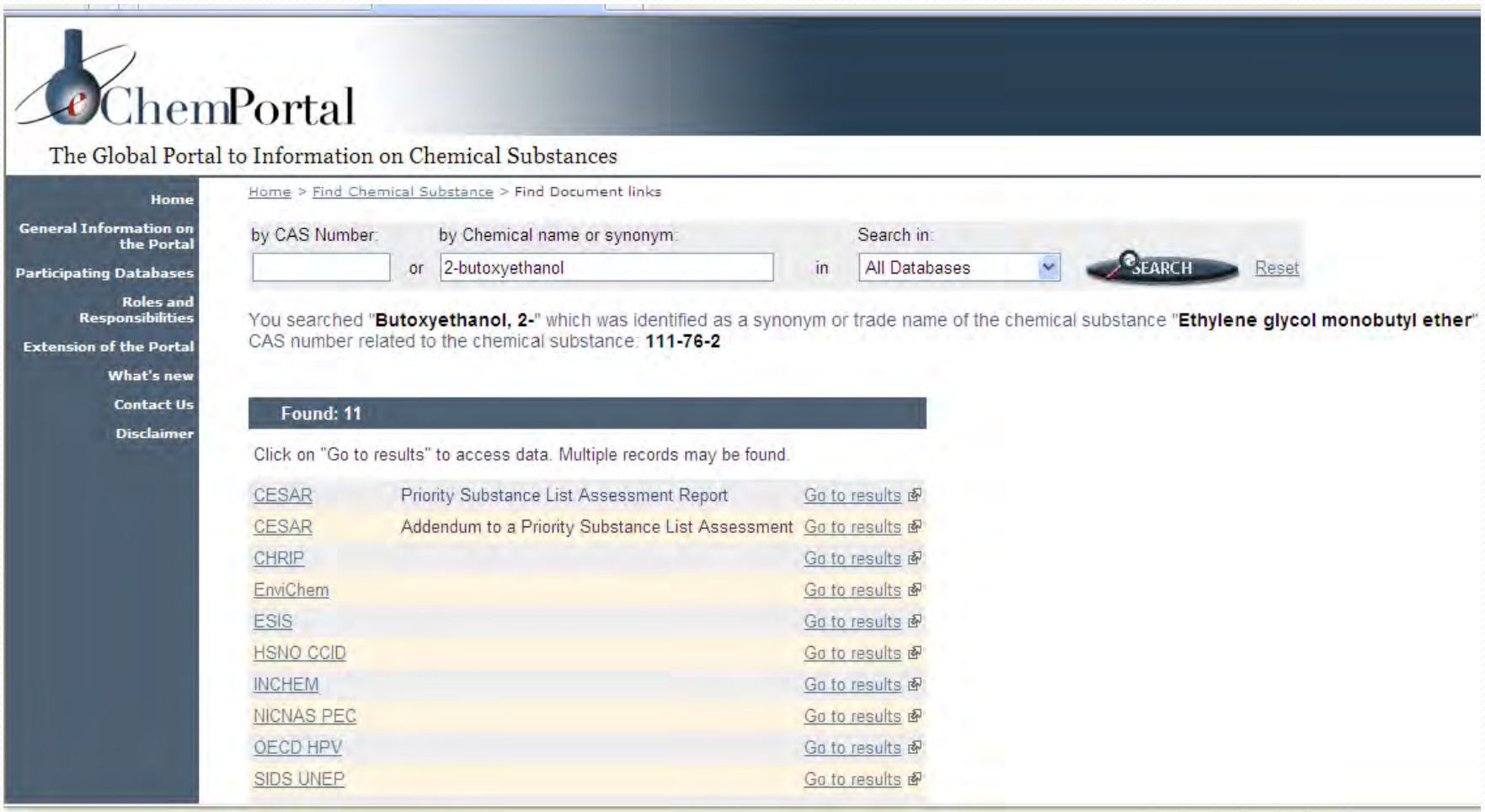
- Address exposure potential
  - Direct (e.g., biomonitoring) and indirect (e.g., production volume)
  - Persistence/bioaccumulation
  - Exposure timing, windows of vulnerability
- Address differential susceptibility
- Dose-response information critical
- Only address hazard, not dose/risk
- Leverage existing data sources
  - Clearly identify data source, potential conflict of interest
- Absence of adequate data a challenge
  - Illustrate data gaps
  - Missing information not necessarily a data gap

Examples of hazard traits

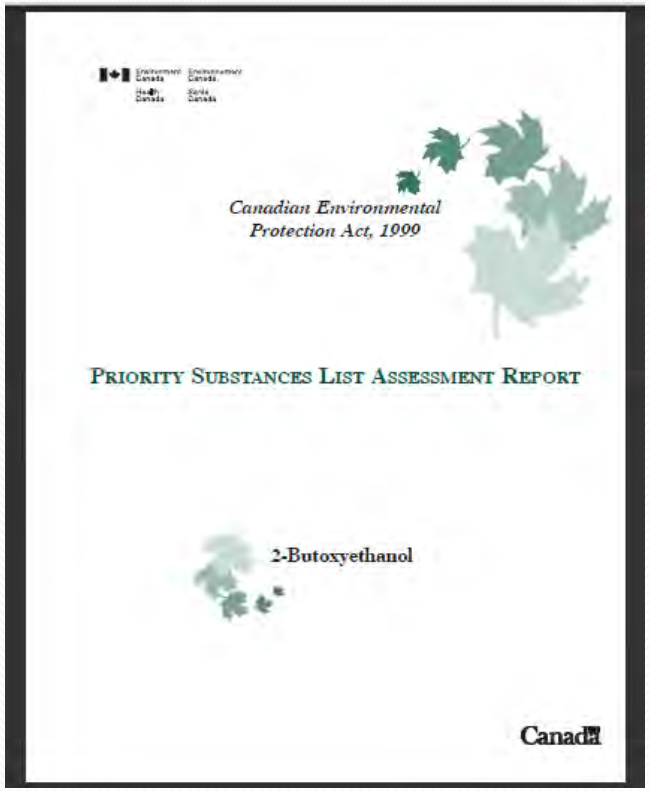
- Carcinogenicity
- Reproductive toxicity
- Developmental toxicity
- Genotoxicity
- Neurotoxicity
- Immunotoxicity
- Respiratory toxicity
- Cardiovascular effects
- Effects on other organs (e.g., liver)
- Endocrine disruption
- Perturbation of other hormone systems
- Ecotoxicity
- Sensory irritation
- Sensitization
- Persistence
- Bioaccumulation
- Flammability
- Reactivity
- Structural alerts
- Other physical chemical properties indicative of a hazard

Two examples of Internet data sources

- OECD eChemPortal
- US EPA Aggregated Computational Toxicology Resource (ACToR)


eChemPortal
The Global Portal to Information on Chemical Substances
Home
General Information on the Portal
Participating Databases
Roles and Responsibilities
Extension of the Portal
What's new
Contact Us
Disclaimer
Home > Find Chemical Substance > Find Document links
by CAS Number:
by Chemical name or synonym:
Search in:
or
2-butoxyethanol
in
All Databases
SEARCH
Reset
You searched "Butoxyethanol, 2-" which was identified as a synonym or trade name of the chemical substance "Ethylene glycol monobutyl ether"
CAS number related to the chemical substance: 111-76-2
Found: 11
Click on "Go to results" to access data. Multiple records may be found.
CESAR Priority Substance List Assessment Report Go to results
CESAR Addendum to a Priority Substance List Assessment Go to results
CHRIP Go to results
EnviChem Go to results
ESIS Go to results
HSNO CCID Go to results
INCHEM Go to results
NICNAS PEC Go to results
OECD HPV Go to results
SIDS UNEP Go to results

eChemPortal: Canada's Existing Substances Assessment Repository



eChemPortal: Japan's Chemical Risk Information Platform

National Institute of Technology and Evaluation
独立行政法人
製品評価技術基盤機構

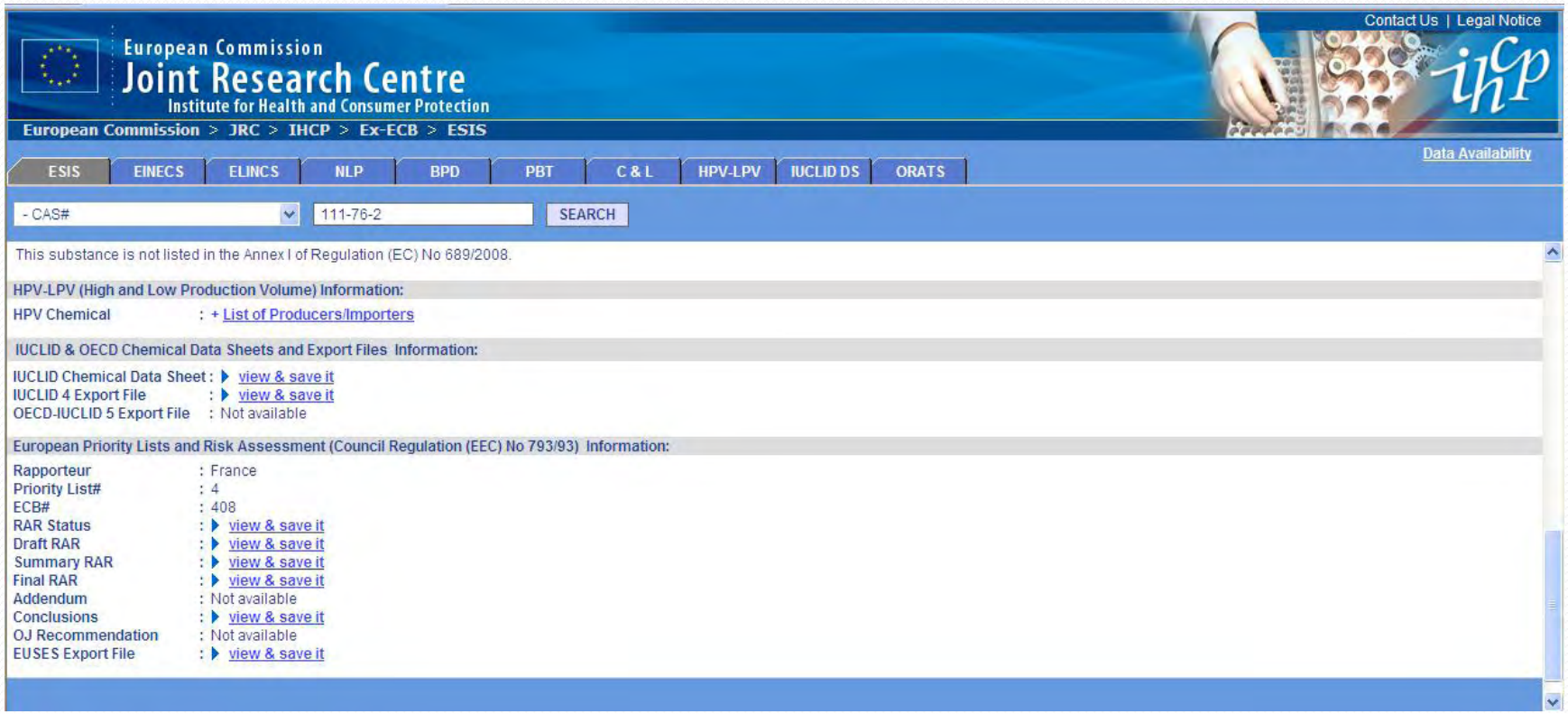
Biodegradation and Bioconcentration of Existing Chemical Substances under the Chemical Substances Control Law

Description Biodegradability

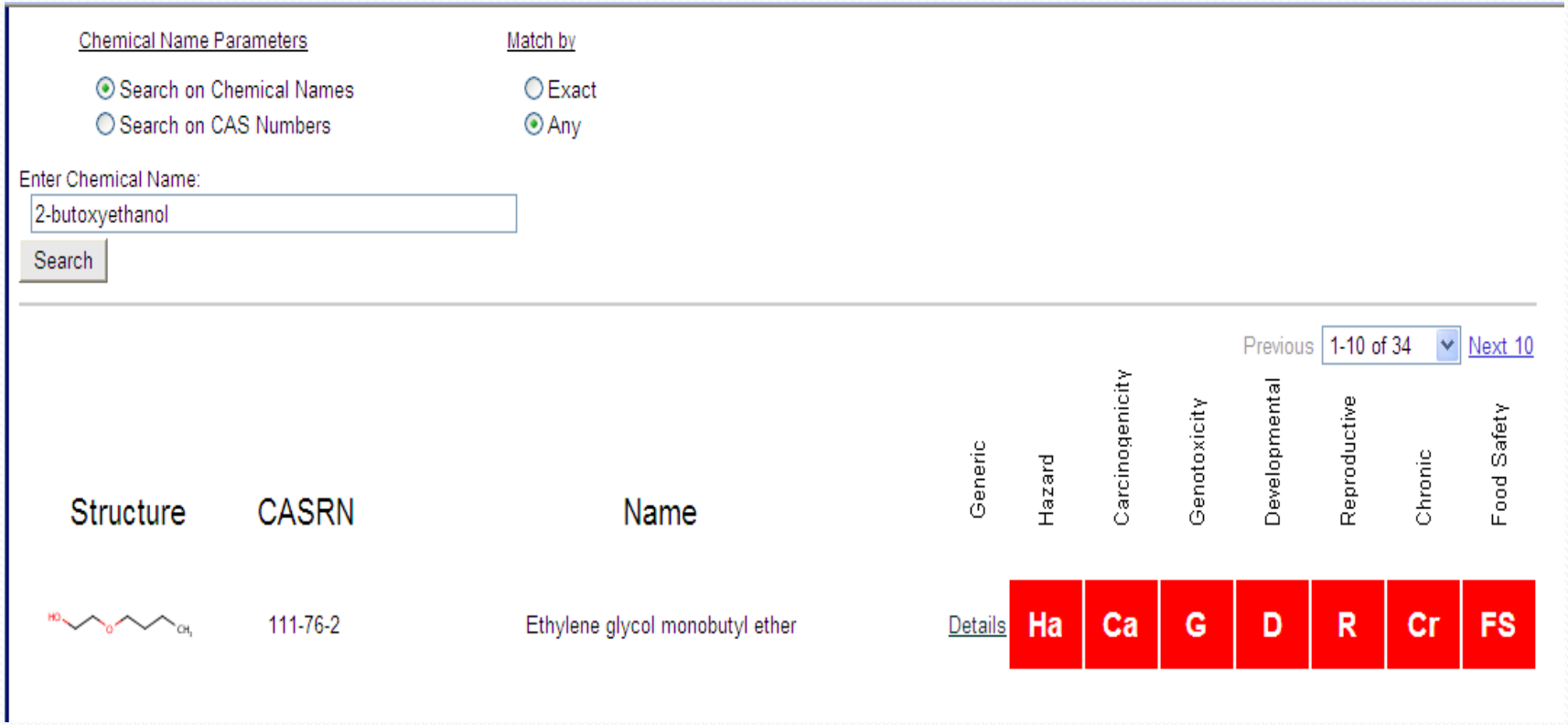
Information on the chemical published in the Official Bulletin of Economy,Trade and Industry (Former title:The Official Bulletin of the Ministry of International Trade and Industry (published before Jan.6,2001))

Published Chemical Name	Published Date	Published result
2-n-butoxyethanol	1976/5/28	Chemical substance determinated to be ready biodegradable

eChemPortal: European Chemical Substances Information System

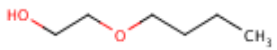


ACToR: Initial search results



ACToR: Chemical summary

Chemical Summary : Ethylene Glycol Monobutyl Ether



GCID	205
CASRN	111-76-2
Formula	C6H14O2
MW	118.1742
SMILES	CCCCOCCO
INCHI	InChI=1/C6H14O2/c1-2-3-5-8-6-4-7/h7H,2-6H2,1H3

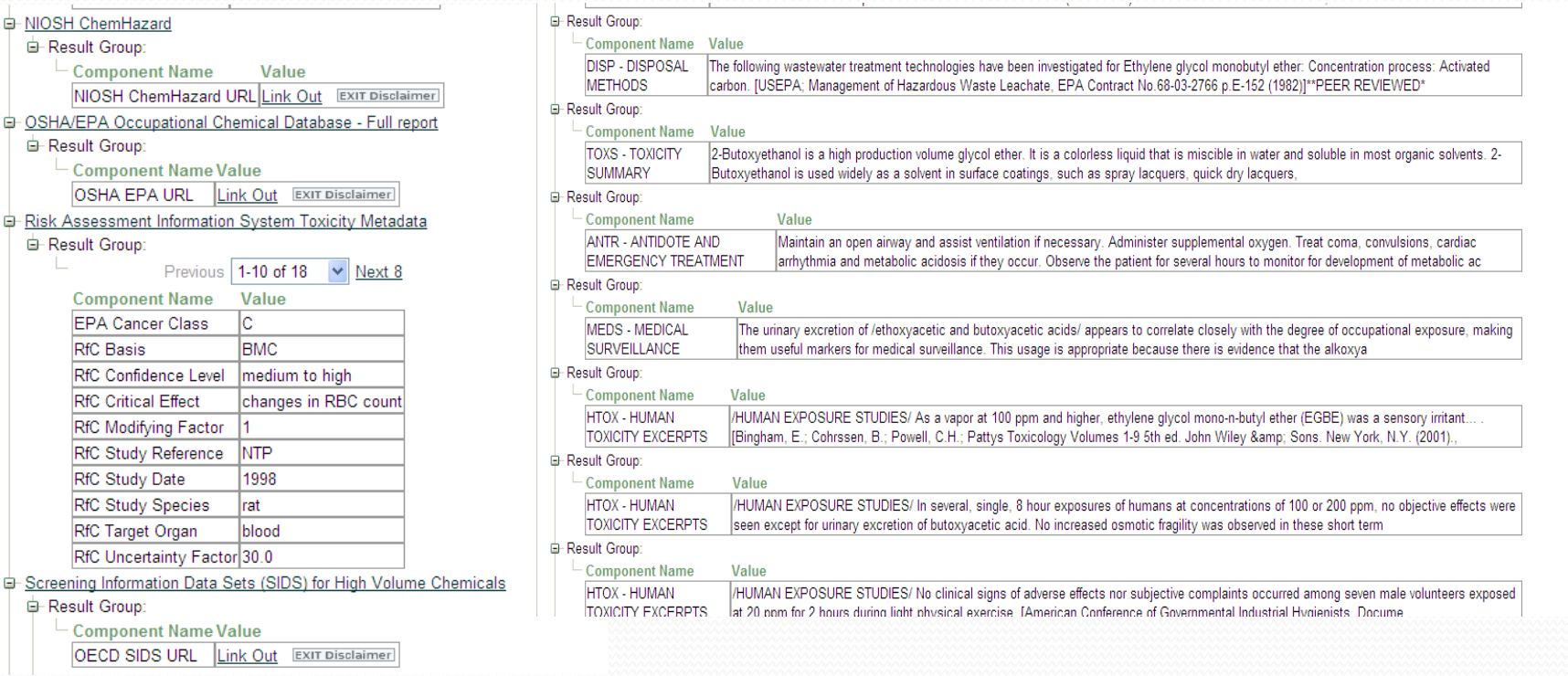
- Show Substances
- Show Synonyms

Data By Toxicology Phenotype
- Show Hazard
- Show Carcinogenicity
- Show Genetic Toxicity
- Show Reproductive Toxicity
- Show Developmental Toxicity
- Show Chronic Toxicity
- Show Food Safety

Data by Toxicology Data Category
- Show In vivo toxicology (tabular, primary data)
- Show In vivo toxicology (tabular, secondary data)
- Show In vivo toxicology (listing of studies performed)
- Show In vivo toxicology (summary calls of toxicity)
- Show In vivo toxicology (links to summary reports on the web)

Non-Toxicology Data
- Show Physico-Chemical Data
- Show Biochemical Assays
- Show Links to chemical summary reports on the web
- Show Chemical Categories
- Show Chemical Manufacturing and Use Levels
- Show Descriptive Data
- Show Pesticidal Mode of Action
- Show Material Safety Data Sheet
- Show Regulations to which chemical is subject
- Show PubMed via MESH
- Show Notes
- Show External Searches by Name or CAS

ACToR: Hazard results (portion)



NIOSH ChemHazard

Result Group:

Component Name	Value
NIOSH ChemHazard URL	Link Out EXIT Disclaimer

OSHA/EPA Occupational Chemical Database - Full report

Result Group:

Component Name	Value
OSHA EPA URL	Link Out EXIT Disclaimer

Risk Assessment Information System Toxicity Metadata

Result Group:

Previous 1-10 of 18 Next 8

Component Name	Value
EPA Cancer Class	C
RfC Basis	BMC
RfC Confidence Level	medium to high
RfC Critical Effect	changes in RBC count
RfC Modifying Factor	1
RfC Study Reference	NTP
RfC Study Date	1998
RfC Study Species	rat
RfC Target Organ	blood
RfC Uncertainty Factor	30.0

Screening Information Data Sets (SIDS) for High Volume Chemicals

Result Group:

Component Name	Value
OECD SIDS URL	Link Out EXIT Disclaimer

Result Group:

Component Name	Value
DISP - DISPOSAL METHODS	The following wastewater treatment technologies have been investigated for Ethylene glycol monobutyl ether: Concentration process: Activated carbon. [USEPA; Management of Hazardous Waste Leachate, EPA Contract No.68-03-2766 p.E-152 (1982)]**PEER REVIEWED*

Result Group:

Component Name	Value
TOXS - TOXICITY SUMMARY	2-Butoxyethanol is a high production volume glycol ether. It is a colorless liquid that is miscible in water and soluble in most organic solvents. 2-Butoxyethanol is used widely as a solvent in surface coatings, such as spray lacquers, quick dry lacquers,

Result Group:

Component Name	Value
ANTR - ANTIDOTE AND EMERGENCY TREATMENT	Maintain an open airway and assist ventilation if necessary. Administer supplemental oxygen. Treat coma, convulsions, cardiac arrhythmia and metabolic acidosis if they occur. Observe the patient for several hours to monitor for development of metabolic ac

Result Group:

Component Name	Value
MEDS - MEDICAL SURVEILLANCE	The urinary excretion of /ethoxyacetic and butoxyacetic acids/ appears to correlate closely with the degree of occupational exposure, making them useful markers for medical surveillance. This usage is appropriate because there is evidence that the alkoxya

Result Group:

Component Name	Value
HTOX - HUMAN TOXICITY EXCERPTS	/HUMAN EXPOSURE STUDIES/ As a vapor at 100 ppm and higher, ethylene glycol mono-n-butyl ether (EGBE) was a sensory irritant... . [Bingham, E.; Cohrssen, B.; Powell, C.H.; Pattys Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001).,

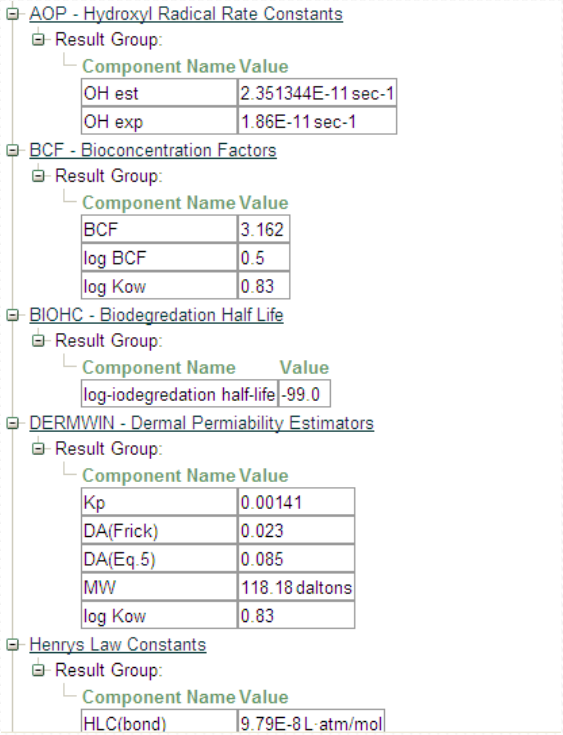
Result Group:

Component Name	Value
HTOX - HUMAN TOXICITY EXCERPTS	/HUMAN EXPOSURE STUDIES/ In several, single, 8 hour exposures of humans at concentrations of 100 or 200 ppm, no objective effects were seen except for urinary excretion of butoxyacetic acid. No increased osmotic fragility was observed in these short term

Result Group:

Component Name	Value
HTOX - HUMAN TOXICITY EXCERPTS	/HUMAN EXPOSURE STUDIES/ No clinical signs of adverse effects nor subjective complaints occurred among seven male volunteers exposed at 20 ppm for 2 hours during light physical exercise. [American Conference of Governmental Industrial Hygienists. Docume

ACToR: Physico-chemical properties (portion)



AOP - Hydroxyl Radical Rate Constants

Result Group:

Component Name	Value
OH est	2.351344E-11 sec-1
OH exp	1.86E-11 sec-1

BCF - Bioconcentration Factors

Result Group:

Component Name	Value
BCF	3.162
log BCF	0.5
log Kow	0.83

BIOHC - Biodegredation Half Life

Result Group:

Component Name	Value
log-iodegredation half-life	-99.0

DERMWIN - Dermal Permiability Estimators

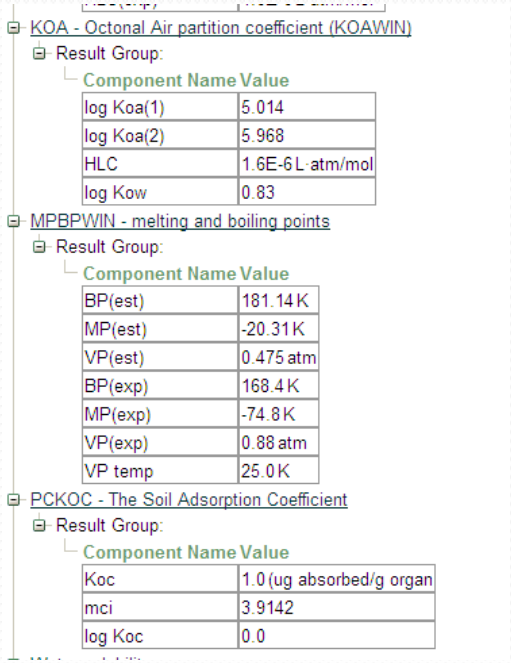
Result Group:

Component Name	Value
Kp	0.00141
DA(Frick)	0.023
DA(Eq.5)	0.085
MW	118.18 daltons
log Kow	0.83

Henrys Law Constants

Result Group:

Component Name	Value
HLC(bond)	9.79E-8 L·atm/mol



KOA - Octonal Air partition coefficient (KOAWIN)

Result Group:

Component Name	Value
log Koa(1)	5.014
log Koa(2)	5.968
HLC	1.6E-6 L·atm/mol
log Kow	0.83

MPBPWIN - melting and boiling points

Result Group:

Component Name	Value
BP(est)	181.14 K
MP(est)	-20.31 K
VP(est)	0.475 atm
BP(exp)	168.4 K
MP(exp)	-74.8 K
VP(exp)	0.88 atm
VP temp	25.0 K

PCKOC - The Soil Adsorption Coefficient

Result Group:

Component Name	Value
Koc	1.0 (ug absorbed/g organ
mci	3.9142
log Koc	0.0

Possible ways that Clearinghouse could add scientific value?

- Include California-specific information
  - New legislation implementing electronic system for California data on hazardous chemicals at regulated sites
- Show relationships between early indicators and toxic effects
- Compare chemicals
  - Data gaps
  - Safer alternatives
- Consider cumulative/synergistic effects

Questions for Panel

- Which are the highest priority hazard traits for inclusion in the Clearinghouse?
- Should the hazard traits be organized and/or evaluated in some way?
- How would you deal with data gaps?
- Which data sources should be included first?

Next steps

- Continue work to evaluate and specify hazard traits
- Hold additional public workshops
- Coordinate with DTSC to:
  - Consult with other state agencies
  - Pursue data sharing with other jurisdictions
  - Seek ongoing input from Panel

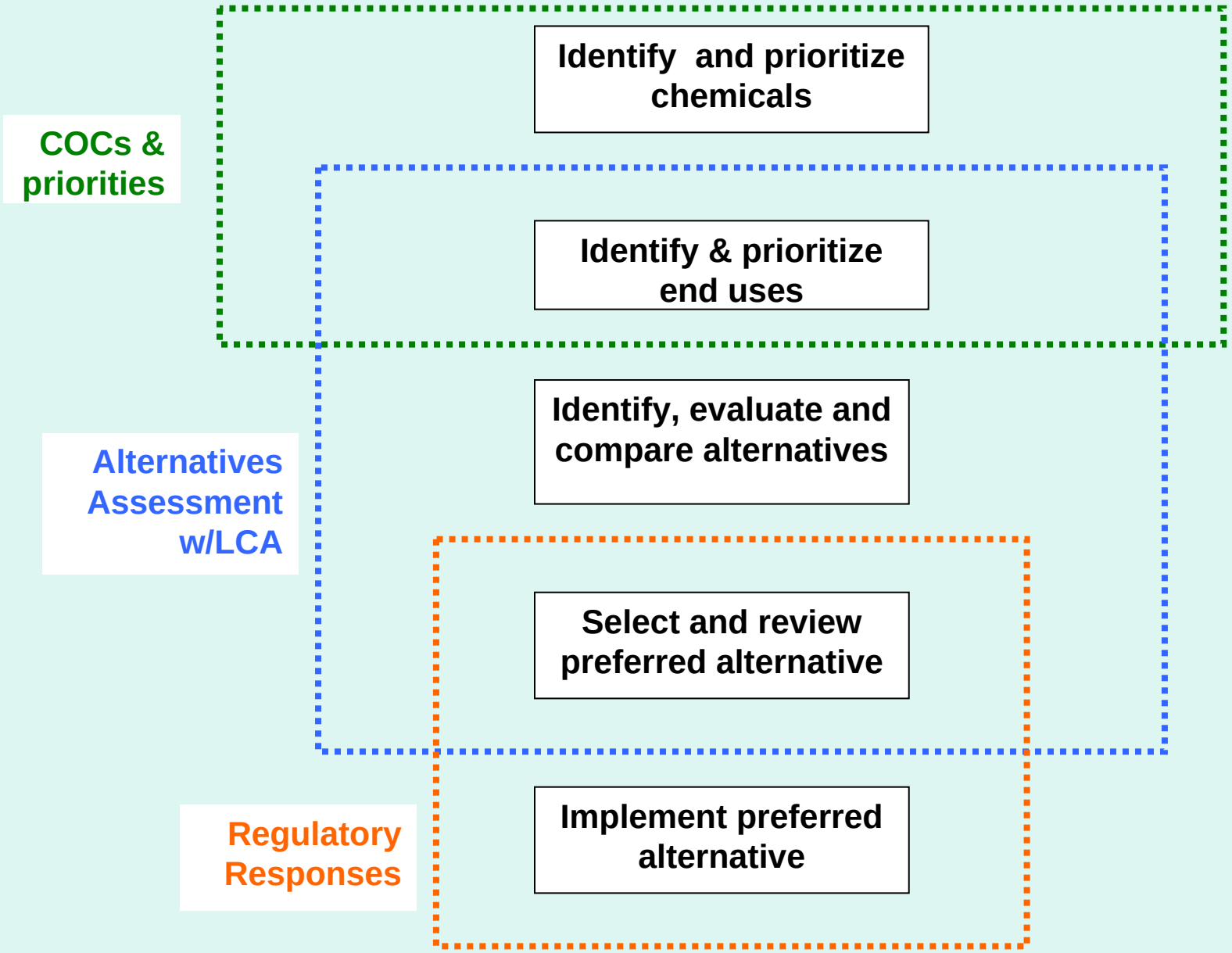
➢ Input welcome: shoover@oehha.ca.gov

Topic 4
Alternatives Assessment with Life Cycle Thinking

Green Ribbon Science Panel

April 29-30, 2009

Regulations for Choosing Safer Alternatives



Alternatives Assessment and Considerations

Determine functionality and need for chemical or product	**Can the product or chemical be replaced, eliminated or otherwise changed?**
Identify potential alternatives	**Is the AA process different for existing alternatives vs. new alternatives?**
Identify positive and negative attributes of alternatives	**Regs can specify attributes; what should be included? Should they be classified as essential and modifying?**
Assess the attributes and compare them	**Regs can specify what should be considered in the assessment and comparison; what should be included?**
Identify safer alternatives	**Regs can specify some of these decision rules; what should they be?**
Select safer alternative	**How can the regulatory responses drive this decision? What info is needed from the AA to inform the regulatory options?**

Alternatives Analysis

- Performed for consumer products that contain one or more high priority chemical of concern
- Ideally performed by “manufacturer”
- Submit to DTSC electronically and post to website for public review and comment
- Ongoing updates

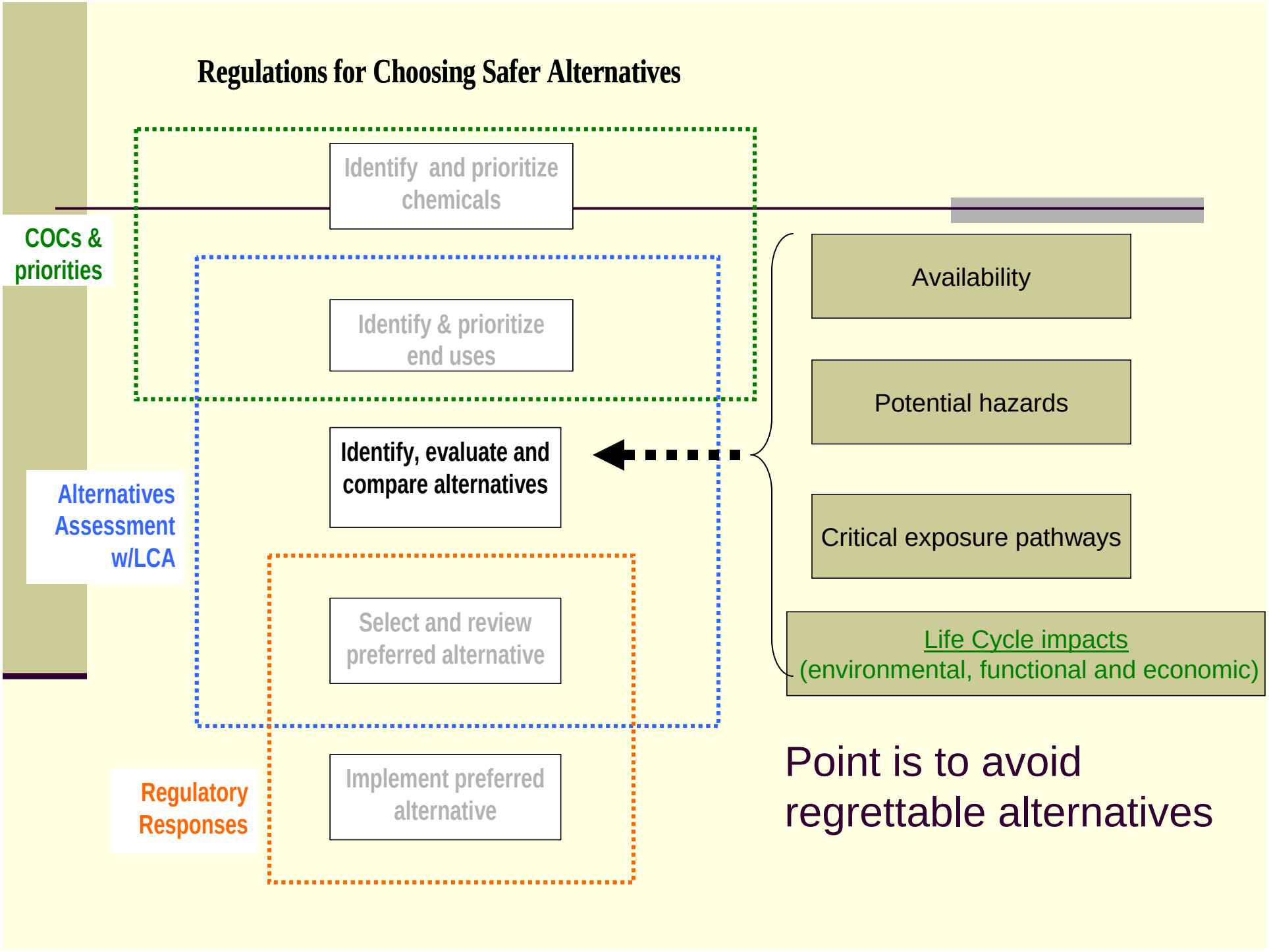
Evaluation Attributes

- Health Impacts
  - Acute and chronic toxicity, carcinogenicity, reproductive hazard, mutagenicity, teratogenicity, endocrine disruption
- Ecological Impacts
  - Aquatic toxicity, persistence, bioaccumulation, mobility
- Potential for Exposure
- Lifecycle Impacts:
  - Product function, useful life, materials/resource consumption, water conservation/quality impacts, air emissions, energy inputs & efficiency, GHG emissions, waste/EOL, public health impacts, environmental impacts, economic impacts

Life Cycle Assessment Guidelines

Within the Framework of Alternative Assessment

Regulations for Choosing Safer Alternatives



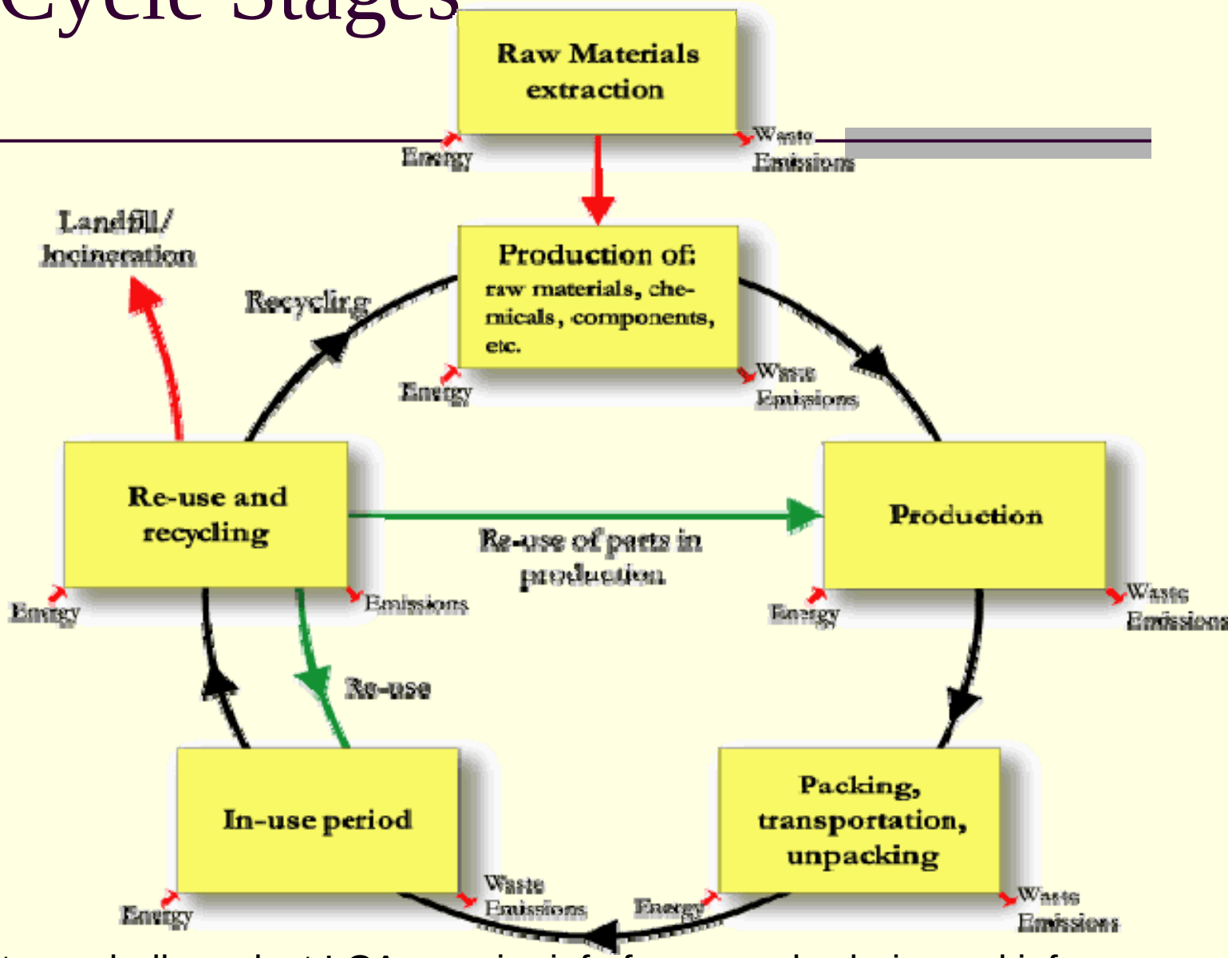
Point is to avoid regrettable alternatives

How to do LCA- Guidelines

1. Determine scope and system boundaries
- Functional unit
- Life-cycle stages
- Define “unit processes” or process description
2. Information collection
3. Assessment of numerous environmental and economic issues/impacts

Note: LCA principles and framework are standardized by the Organization for International Standardization’s 14040 series of standards (ISO 14040)

Life Cycle Stages



Product manufacturer shall conduct LCA, require info from supply chain, and inform retailers, importers, distributors and consumers.

Life Cycle Impacts

- §25253 (a) (2) … life cycle assessment tools take into consideration, but shall not be limited to, all of the following:

  (A) Product function or performance.
  (B) Useful life.
  (C) Materials and resource consumption.
  (D) Water conservation.
  (E) Water quality impacts.
  (F) Air emissions.
  (G) Production, in-use, and transportation energy inputs.
  (H) Energy efficiency.
  (I) Greenhouse gas emissions.
  (J) Waste and end-of-life disposal.
  (K) Public health impacts, including potential impacts to sensitive subpopulations, including infants and children.
  (L) Environmental impacts.
  (M) Economic impacts.

Level of Analysis: Qualitative Life Cycle Thinking vs. Quantitative Full LCA

Options	Pros	Cons
Qualitative life-cycle framework approach	■ Most expedient and ■ Lowest skill needed ■ Protects confidential data ■ Use data publically available	■ Reliant on the practitioner's judgment ■ Least informative ■ Difficult to verify/validate ■ Difficult to ensure consistency and comparability
Conventionally full quantitative LCA	■ Best method to assure goals ■ Most informative	■ Most resource intensive and costly; require highest skill ■ Time consuming, may delay implementation ■ Data may not available; assumptions need to be valid
Semi-quantitative / qualitative LCA (hybrid) (Recommended approach with certain QA/QC measures)	■ Assure goals in most circumstances ■	■ Less resource intensive and costly; require less skill ■ May be difficult to establish mechanism/criteria ■ Reasonable data quality remains

Our approach -

- **“Guideline for application of life-cycle methodology to alternatives assessment”**
  - to provide a flexible integrated framework

- **How are LCA results informative**

-identify life cycle “hot spots” and lead to improvements

-support to determine feasibility of alternatives

Conduct Evaluation

- Identify availability of potential alternatives
- Collect info for specified attributes
- Conduct LCA
- Stepwise comparison
  1) Compare according to prioritization criteria
  2) Compare according to health & eco criteria
  3) Compare using other lifecycle impact criteria and principles of green chemistry

Questions

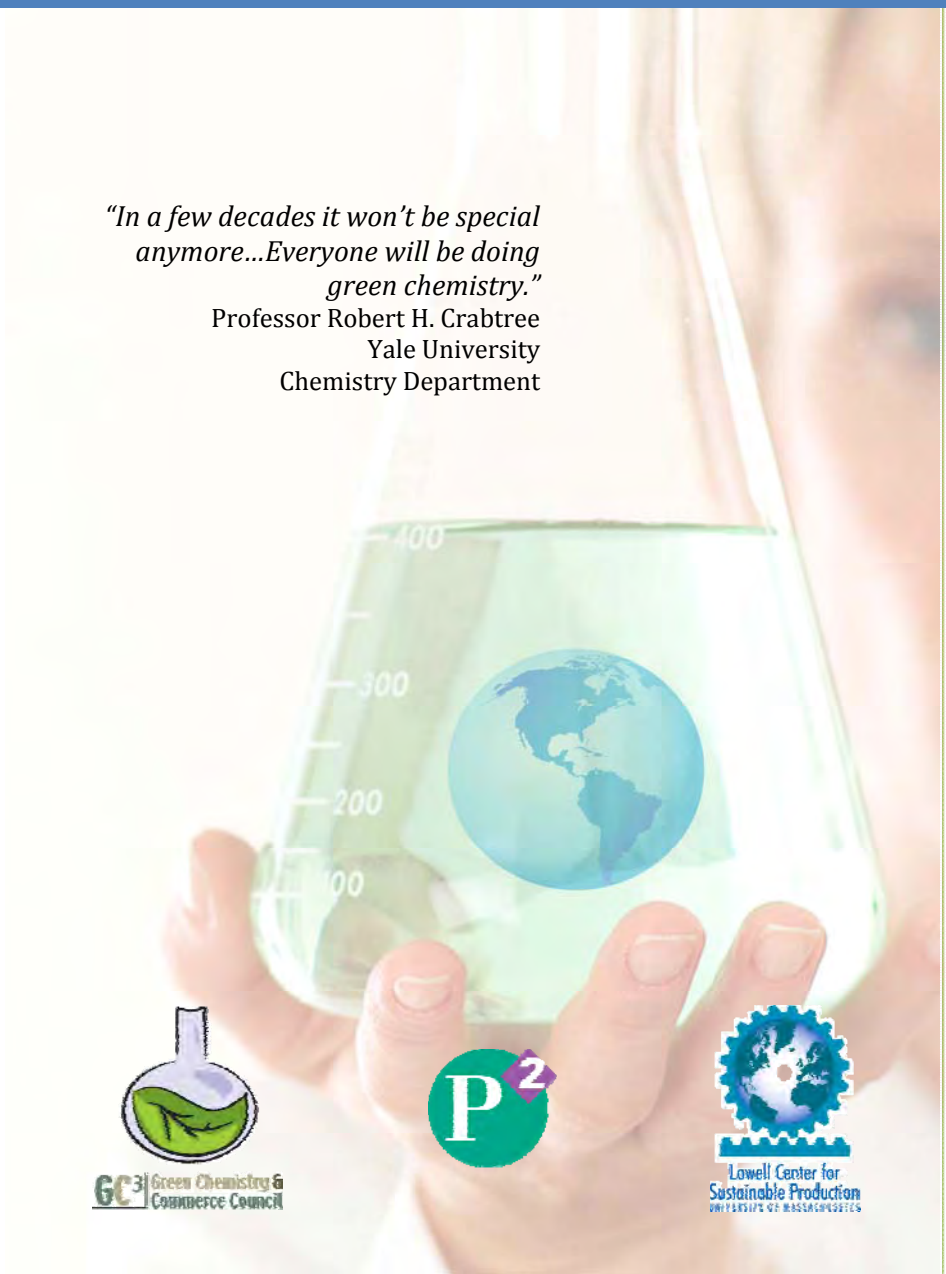
- Functional equivalency & feasibility of alternatives?
  - Criteria to determine functional equivalency and feasibility?
- Third party involvement or role?
  - How could this work, for preparing/reviewing?
  - Ideas for choosing, screening, evaluating, qualifying, training third parties?
- Choosing an alternatives analysis model?
  - Criteria to choose a model?
- Comparing dissimilar attributes?
  - Ideas for decision rules/preferences?
  - Ideas for conducting expedited comparisons?

A Resource Guide for States and Higher Education

2009

Growing the Green Economy Through Green Chemistry and Design for the Environment

"In a few decades it won't be special anymore…Everyone will be doing green chemistry."
Professor Robert H. Crabtree
Yale University
Chemistry Department



GC3 Green Chemistry & Commerce Council

P2

Lowell Center for Sustainable Production
UNIVERSITY OF MASSACHUSETTS

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Growing the Green Economy

Through Green Chemistry and Design for the Environment

A Resource Guide for States and Higher Education

A joint report by
The Green Chemistry and Commerce Council
and The National Pollution Prevention Roundtable

A project of the Lowell Center for Sustainable Production

Publication support provided by the
Washington State Department of Ecology

The Green Chemistry and Commerce Council (GC3) was formed in 2005 and provides an open forum for participants to discuss and share information and experiences relating to advancing green chemistry and design for the environment as it pertains to sustainable supply chain management.

The mission of the GC3 is to promote and support green chemistry and design for the environment approach to research and practices nationally and internationally among companies and other governmental and non-governmental entities by:

- Implementing green chemistry, green engineering, and design for the environment throughout supply chains and sharing strategies to overcome barriers and reduce environmental footprints.
- Promoting education and information on safer chemicals and products that can increase demand by a broad range of consumers.
- Identifying existing and needed information on toxics hazards, risks, exposures, and safer alternatives to promote green chemistry as defined in the *12 Principles of Green Chemistry*.

The **National Pollution Prevention Roundtable** (NPPR), a 501(c)(3) non-profit organization, is the largest membership organization in the United States devoted solely to pollution prevention (P2). The mission of the Roundtable is to provide a national forum for promoting the development, implementation, and evaluation of efforts to avoid, eliminate, or reduce pollution at the source.

NPPR promotes the development, implementation, and evaluation of efforts to avoid, eliminate, or reduce waste generated to air, land, and water. The sustainable and efficient use of energy, materials, and resources is vital to the protection and enhancement of human health and the environment, and the conservation of natural resources. These efforts are integral to accelerate the shift towards sustainable consumption and production to promote environmentally responsible social and economic development.

The Lowell Center for Sustainable Production facilitates the Green Chemistry and Commerce Council. It uses rigorous science, collaborative research, and innovative strategies to promote communities, workplaces, and products that are healthy, humane, and respectful of natural systems. The Center is composed of faculty, staff, and graduate students at the University of Massachusetts Lowell who work collaboratively with citizen groups, workers, businesses, institutions, and government agencies to build healthy work environments, thriving communities, and viable businesses that support a more sustainable world.

The objectives of LCSP 's Chemicals Policy and Science Initiative are to:

- Significantly advance policy dialogue on reforming chemicals policy in the United States.
- Assist in the development of sustainable chemicals management outside the US.
- Encourage the development and use of safer alternatives by creating and promoting a comprehensive framework for alternatives assessment.
- Identify tools and appropriate ways of assisting green chemistry innovation and safer supply chain management of chemicals.

This guide is available on:

- The Green Chemistry and Commerce Council (GC3) website at www.greenchemistryandcommerce.org/publications.php
- The National Pollution Prevention Roundtable website at www.p2.org

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Introduction

For more than fifteen years, green chemistry (GC) and design for the environment (DfE) have successfully been used to benefit the environment and the economy. The Green Chemistry and Commerce Council (GC3) and the National Pollution Prevention Roundtable (NPPR) developed this guide to further entrench these approaches as the bedrock of industry practices and government policies regarding chemical and materials selection. The guide outlines options for states to promote research, development and use of GC and DfE to:

- Eliminate or reduce the use or generation of hazardous chemicals in manufacturing.
- Promote the development of the green economy.

Washington State describes "greening" the economy as developing new products, techniques, and services that promote a healthy environment and energy security. The global market for green economy technology has grown for seven straight years. The $8.4 billion invested in North America, Europe, China, and India in 2008 increased by 38 percent from 2007, according to The Cleantech Group LLC. The fastest growing sectors included:

- Energy generation
- Energy storage
- Transportation
- Energy efficiency
- Recycling and waste treatment

The current federal and many state's emphasis on green economic growth provides an opportunity for the GC3-NPPR partnership to assist in the advancement of GC and DfE approaches. Many of the federal and state efforts focus on "green collar job programs" for energy efficiency and renewable energy. In addition to the development of clean technology, GC and DfE approaches offer significant opportunities for:

- Safer chemicals and products to advance clean energy.
- Green building.
- Green transportation and environmental protection.
- Safer jobs.
- Safer consumer products.

The American Chemistry Council estimates that each job in chemistry generates 5.5 additional jobs elsewhere in the economy. When applied, many of the options outlined in this guide will:

- Create new "green jobs" (e.g., manufacturing positions, university researchers).
- Retain existing jobs by redefining job responsibilities (e.g., environmental agency staff).

- Assist companies to thrive by redefining themselves as green (e.g., business tax incentives).
- Stimulate the local economy (e.g., new enterprises, conferences).

This guide will help state governments promote green practices, create green economic opportunities, and move national policy forward by:

- Defining and presenting examples of GC and DfE examples.
- Presenting options for states to use, such as development, collection, and dissemination of information; economic incentives; recognition programs; and regulations and policies.
- Presenting roles for education institutions, a vital partner in this effort.
- Identifying available resources and tools.

Defining Green Chemistry and Design for the Environment

As states consider promoting these approaches, clear and consistent definitions of GC and DfE are essential.

Green Chemistry

Green chemistry is an approach to chemistry that uses the 12 Principles of Green Chemistry. It reduces or eliminates the need for and generation of hazardous materials during the manufacture, design, and application of chemistry. The GC3 and NPPR are committed to applying the 12 Principles below in chemical process and product design:

1. Prevent waste: Design chemical syntheses to prevent waste, leaving no waste to treat or clean up.
2. Design safer chemicals and products: Design chemical products to be fully effective, yet have little or no toxicity.
3. Design less hazardous chemical syntheses: Design syntheses to use and generate substances with little or no toxicity to humans and the environment.
4. Use renewable feedstocks: Use raw materials and feedstocks that are renewable rather than depleting. Renewable feedstocks are made from agricultural products or the wastes of other processes. Depleting feedstocks are made from fossil fuels (petroleum, natural gas, or coal) or are mined.

5. Use catalysts, not stoichiometric reagents: Minimize waste by using catalytic reactions. Catalysts are used in small amounts and can carry out a single reaction many times. They are preferable to stoichiometric reagents, which are used in excess and work only once.
6. Avoid chemical derivatives: Avoid using blocking or protecting groups or any temporary modifications if possible. Derivatives use additional reagents and generate waste.
7. Maximize atom economy: Design syntheses so that the final product contains the maximum proportion of the starting materials. There should be few, if any, wasted atoms.
8. Use safer solvents and reaction conditions: Avoid using solvents, separation agents, or other auxiliary chemicals. If these chemicals are necessary, use innocuous chemicals.
9. Increase energy efficiency: Run chemical reactions at ambient temperature and pressure whenever possible.
10. Design chemicals and products to degrade after use: Design chemical products to break down to innocuous substances after use so they do not accumulate in the environment.
11. Analyze in real time to prevent pollution: Include in-process real-time monitoring and control during syntheses to minimize or eliminate the formation of byproducts.
12. Minimize the potential for accidents: Design chemicals and their forms (solid, liquid, or gas) to minimize the potential for chemical accidents including explosions, fires, and releases to the environment.

According to the Michigan Green Chemistry Roundtable, the scope and boundaries of a Green Chemistry Program should:

- Consider all the stages of the life cycle of a chemical.
- Focus on "hazard reduction" as the primary impact category of interest in each life cycle stage with a focus on the design stage. Other life cycle impacts of innovation should also be considered.
- Reduce hazards to human and ecosystem health.

Design for the Environment

Co-pioneered by industry, the DfE concept encourages businesses to incorporate environmental and health considerations in the design and redesign of products and processes. It is the systematic assessment of human health and safety and environmental issues during the product development phase. Designing for the environment improves environmental and human health and increases product performance and market competitiveness. The focus is on finding sustainable solutions to identified materials of concern. In essence, DfE represents the application of green chemistry in practice.

The DfE program of the U.S. Environmental Protection Agency (EPA) works with a broad range of stakeholders to reduce human and environmental risks by preventing pollution. Industry representatives and environmental groups convene to develop goals and guide the work of the partnership. Partnerships evaluate the human health and environmental considerations, performance, and cost of traditional and alternative chemicals, materials, technologies and processes.

EPA has formed numerous DfE partnerships with electronics, wire and cable, furniture and automobile refinishing industries, and focuses on such issues, such as lead-free solder, safer flame-retardants and best business practices.

As an incentive for taking part, DfE offers technical tools, methods, and expertise. The DfE Program uses the unique chemical assessment tools and knowledge of EPA's Office of Pollution Prevention and Toxics to inform industries about substitution in processes and using green chemistry in products.

In certain sectors, EPA DfE partners can receive EPA recognition or use the DfE label on environmentally improved products. The DfE logo on a product signifies that the DfE scientific review team has screened each ingredient and has judged that the product's ingredients all pose the least concern among chemicals in their class.

In the Formulator Program, EPA's DfE Program joined manufacturers of chemically-blended products to improve their human health and environmental profile. Their work benefits the biodegradability of waste streams, aquatic life, and other elements of the environment, as well as human health and safety. This type of DfE partnership focuses on selecting the safest possible ingredients to create high-performing, cost-effective products. DfE can provide:

- Information on chemical characteristics.
- Toxicity of raw materials and additives.
- Safer substitutes for chemicals of concern.
- Innovative new chemistries.

Through the Safer Detergents Stewardship Initiative (SDSI), EPA's DfE Program recognizes environmental leaders who voluntarily commit to the use of safer surfactants. Safer surfactants break down quickly into non-polluting compounds and help protect aquatic life in both fresh and salt water.

Examples of Green Chemistry and Design for the Environment Successes

- A more effective fire extinguishing agent that eliminates halon and uses water in combination with an advanced surfactant.
- Removal of arsenic from wood preservatives used on lumber for decks and playground equipment.

- Higher performance automotive coatings that remove substantial lead content and replace it with the relatively benign element yttrium.
- From 1996-2008, projects that received the EPA Green Chemistry Presidential Awards
  - Eliminated over 1.1 billion pounds of hazardous chemicals and solvents.
  - Reduced releases of nearly 400 million pounds of carbon dioxide to air.
  - Saved over 21 billion gallons of water.
- Use of the DfE label on about 1,000 products that have been reformulated to be environmentally safer, cost competitive, and effective represents a reduction of more than 270 million pounds of chemicals of concern.
- Recognition by EPA of 40 champions (highest level), and 22 partners who committed to using safer surfactants through the Safer Detergents Stewardship Initiative.
- Development of a database of safer cleaning-product ingredients called CleanGredients through an EPA partnership with the GreenBlue Institute. As of 2009, 27 chemical manufacturers paid to list 138 chemicals, and more than 327 formulators paid to use the system.
- Assisted by EPA's DfE multi-stakeholder alternatives analyses, industries have moved to safer flame-retardants in furniture and reduced the use of lead in electronics. The analyses also provided information on personal protective equipment and management practices to minimize risks associated with chemical exposures at nail care facilities.

Methods for States to Advance Green Chemistry and Design for the Environment

State governments have a unique opportunity to promote safer chemical processes and products and the growth of the green economy by advancing green chemistry and design for the environment.

Each state's goals and capabilities will dictate which of the following methods is appropriate; it is not necessary to use all of them. Some options are more costly and more difficult than others, depending on the nature of the method and a state's political climate and resources.

It is also important for states to consider existing federal and state GC and DfE programs when developing new initiatives to assure consistency, to the extent practicable. This will reduce confusion and cost, and lead to the highest possible standards. Current programs include:

- The Michigan Green Chemistry Program.
- The California Green Chemistry Initiative.
- EPA's Design for the Environment and Green Chemistry Programs.

If a state wishes to develop a comprehensive program, the first step may be to establish a green chemistry initiative or program by executive directive or other appropriate legislative means. The initiative would then be used to coordinate the specific elements chosen. This is not a necessary step however, and adopting just a few or even one of the options below can yield large gains in promoting GC and DfE approaches.

■ Information Development, Collection, and Dissemination

- **Establish a green chemistry and design for the environment program, initiative, institute or task force.** This could serve as the coordinating body to engage stakeholders and share knowledge, tools, and experience. An institute could provide technical research to identify and replace "chemicals of concern" with safer chemical or non-chemical alternatives. A task force could design an action plan for the state, set policies, and develop criteria for other components of the effort. A university, non-governmental organization, or a state environmental or health agency could house the program, institute, or task force. For example: Michigan's Green Chemistry Program is part of the Michigan Department of Environmental Protection, and California's Green Chemistry Initiative and the Green Ribbon Science Panel are housed at the California Department of Toxic Substances Control.

- **Integrate green chemistry and design for the environment into active pollution prevention technical assistance programs.** Develop green chemistry and design for the environment expertise in existing pollution prevention and manufacturing technical assistance programs. This may involve hiring or training staff on characterizing hazards and risks and life-cycle analysis to reduce the use of and exposure to chemicals of concern. Once the expertise is developed, it should be integrated into existing services, such as on-site technical assistance, workshops, and guidance manuals. Disseminating case studies will provide ideas and motivational incentives. Example: The Massachusetts Office of Technical Assistance developed GC and DfE expertise and offers these services to Massachusetts businesses.

- **Convene a green chemistry and design for the environment conference.** A conference can provide a forum for sharing successes and strategies, and can assist in creating a network to support the initiative. This can also be an opportunity to identify industry research needs to assist in a state's preparation of requests for proposals for funds. (See Research and Development Fund under Economic Incentives heading.) Example: California Green Chemistry Symposiums I, II, and III. Similarly, a state could add a GC or DfE session at an established conference on related topics. Example: Arizona's Green Summit.

- **Create a resource clearinghouse for green chemistry and design for the environment activities.** Compile research, development, use, and education information about GC and DfE efforts into a single location. The clearinghouse could host a listserve for timely sharing of ideas and successes and to further develop the network of state support for GC and DfE. Related example: The University of

Oregon's Greener Education Materials for Chemists is a database of green chemistry education materials.

- **Promote chemical information and alternatives assessment.** Support the sharing of information and tools, such as chemical use, toxicity, hazards, exposure, and alternatives, as well as methods to reduce the use of and exposure to chemicals of concern and to design safer chemistries. Example: The Interstate Chemical Clearinghouse (IC2) is under development, established by a partnership of states to promote a clean environment, healthy communities, and a vital economy through the development and use of safer chemicals and products.

- **Issue public service announcements and information on the value of green chemicals and products.** Raise public awareness about the importance and availability of green products through radio, television, websites, or printed materials.

■ Economic Incentives

- **Create a green chemistry and design for the environment research and development fund.** Establish a state grant fund to promote green chemistry research. Select proposals in consultation with a higher education expert review panel. Other similar options include a green chemistry research challenge or public-private research partnerships. Example: The Green Chemistry Research Fund was identified as an option in "Green Chemistry Options for the State of California." States may also tailor existing programs to fund GC and DfE research. Example: New York Empire State Development offers funding for projects that produce measurable results in pollution prevention, reuse, and recycling.

- **Provide green chemistry and design for the environment tax incentives.** Support research and development efforts of companies attempting to develop and market safer, less toxic products through targeted tax breaks. Related example: The Washington Business and Occupation Tax Incentive for High Technology is an annual credit of up to $2 million for research and development in specific high technology categories, including environmental technology.

- **Provide investment tax credits, low-interest loans, loan guarantees, or subsidies for green chemistry manufacturing equipment or products.** Make financial capital available to companies at preferential terms through the means chosen to encourage GC and DfE. Examples : "Green Chemistry Options for the State of California" discusses this option. France offers reduced-interest loans to businesses investing in the production of green products.

- **Promote green chemistry and design for the environment through incentives tied to economic development projects.** Promote GC and DfE through existing

economic development projects, such as industrial parks, brownfields, or low-impact development. Example: "The Modernizing Washington Manufacturers" program provides $2 million for modernizing existing manufacturing processes, retaining jobs, and transforming them to "green" jobs through the existing Washington Manufacturing Services Fund.

■ Recognition Programs

- **Implement green chemistry and design for the environment awards program.** Recognize excellence, innovation, economic development and public health risk reduction by businesses and institutions through an awards program. Examples: EPA Presidential Green Chemistry Challenge Awards, and the planned Michigan Green Chemistry Awards. Another option is to add a GC or DfE category to an existing environmental awards program. Example: Texas Environmental Excellence Awards.

- **Recognize top poster displays at conferences.** Issue awards to the top GC and DfE poster displays at conferences to promote the concepts and to foster ideas and information sharing.

■ Regulation and Policy Tools

- **Require environmentally responsible state purchasing.** Require that state agencies buy the least toxic products available when performance and price are comparable, with a preference for products made locally. See Appendix A for descriptions of the three principal third-party programs for use by states to identify green products (EcoLogo, Green SealTM, EPA's DfE Formulator Program). Examples: Environmentally Preferable Purchasing Programs in Washington and New York states.

- **Apply fee or tax to substances of high concern.** Encourage green chemistry research and the use of less hazardous chemicals by increasing the cost of these substances of concern. Related example: Tax on cigarettes. The fees could fund technical assistance or research into safer alternatives. Example: Massachusetts Toxics Use Reduction Act.

- **Negotiate supplemental environmental projects focused on GC and DfE in enforcement settlements.** Ensure that projects are focused on developing or demonstrating new GC or DfE technology when incorporating supplemental environmental projects into enforcement settlements. Example: EPA has used this strategy for pollution prevention projects in enforcement settlements since 1989.

- **Prepare GC action plans for chemicals of high concern.** Outline alternatives and action steps to minimize use of chemicals identified. Action steps could include demonstration projects, state procurement programs, data collection on use, dialogs with industry suppliers, and mandatory requirements for substitution. Examples: The Mercury Chemical Action Plan and Polybrominated Diphenyl Ether (PBDE) Chemical Action Plan of Washington State.

- **Require safer alternatives planning.** Through statute, require companies using certain chemicals at certain volumes to conduct a chemical use inventory and safer alternatives plan. Example: Massachusetts Toxics Use Reduction Act.

- **Restrict chemicals or products of concern.** Use existing or new legislation to restrict specific chemicals or product categories in ways that create markets for safer substitutes. Example: California, Maine, and Washington are among states that have passed laws phasing out the use of the flame-retardant polybrominated diphenyl ethers.

- **Prepare list of chemicals of concern.** List chemicals that should be avoided where possible. They signal potential regulatory actions that could encourage green chemistry research and shifts in chemical preferences. Example: California Prop 65 list. States can also require authorization to use these chemicals. Example: REACH Authorization Process.

- **Promote DfE by implementing policies that support producer responsibility and closed loop management of chemicals and materials.** This will reduce exposure and toxics use and encourage recycling. Example: Electronic waste take-back programs.

The Roles of Educational Institutions

Educational institutions are vital to furthering the GC and DfE approaches by:

- Educating the future workforce of the green economy.
- Discovering new green chemistry and product options.
- Supporting efforts to overcome application challenges.
- Analyzing policy options.
- Serving as the host for needed dialogues between researchers and businesses and communities.

States can partner with or pursue policies that support educational institutions in these endeavors:

- **Create a green chemistry education network.** Provide a link for teachers at different levels to share curriculum, training tools, and strategies. Examples: The

Green Chemistry Education Network facilitated by the University of Oregon's Department of Chemistry is specific to the issue. The New England Association of Chemistry Teachers houses the network within the organization. Beyond Benign has developed curriculum and education resources for middle and high schools. The University of Oregon's Greener Education Materials for Chemists is a database of green chemistry education materials.

- **Offer GC and DfE college courses.** Higher education institutions can offer green chemistry, toxicology, and environmental science and policy courses as part of the chemistry curriculum. Examples: The New York Pollution Prevention Institute is developing a green chemistry higher education curriculum. Existing resources include the University of Oregon's Greener Education Materials for Chemists, a database of green chemistry education materials.

- **Provide GC and DfE scholarships, internships, and graduate student support.** This is an inexpensive method for encouraging students to become eager promoters of new approaches. Example: "Green Chemistry Options for the State of California" discusses this option.

- **Encourage K-12 education programs.** University courses with a focus on GC and DfE could require students and staff to conduct outreach to local high schools and primary schools teaching green chemistry. Example: The New York Department of Environmental Conservation is working with the New York Education Department and the New York Pollution Prevention Institute on developing a green chemistry lab manual for high schools. Existing resources include curriculum and education resources for middle and high schools developed by Beyond Benign.

- **Establish a consortia of state research universities to support green chemistry.** Higher education institutions can form strategic partnerships and alliances to educate, discover, develop, apply and promote GC and DfE. Use existing green chemistry faculty and research groups where they exist. Example: The New England Green Chemistry Consortium

- **Convene innovation-focused industry dialogues.** Higher education institutions can facilitate discussions with industry on GC and DfE topics. This will build the network and can be a forum for identifying GC and DfE research needs and sharing successes. Example: The Green Chemistry and Commerce Council established by the Lowell Center for Sustainable Production at the University of Massachusetts Lowell.

- **Host a symposium for industry.** This would allow the educational institution to showcase GC and DfE research and innovations to industry and increase networking opportunities. This would also link industry research needs to researcher expertise. Examples: The Northern Essex Community College Technology Center's Green Chemistry Business Summit and Gordon Research Conference – Green Chemistry at Bates College.

CG and DfE Information Toolbox

Green Chemistry

A number of informational tools are available to assist businesses in applying green chemistry methods, such as:

- EPA's **Green Chemistry Expert System**, a computer program that can be used to select green chemicals and reactions. It includes the Synthetic Methodology Assessment for Reduction Techniques (SMART) module that quantifies and categorizes the hazardous substances used in or generated by a chemical reaction based on information provided by the user. Reactions can be modified and reevaluated to optimize their green nature. www.epa.gov/greenchemistry/pubs/gces.html

- Massachusetts Institute of Technology's **Green Chemistry Alternatives Wizard**, a web-based tool that allows the user to search from a select list of common solvents, and the associated process. The Wizard identifies less hazardous and more environmentally benign chemicals or processes that may be substituted. http://web.mit.edu/environment/academic/purchasing.html

- **CleanGredients®**, a project of the nonprofit Green Blue Institute (GreenBlue®), is an online database of cleaning product ingredient chemicals that meet established requirements for superior environmental and human health performance. CleanGredients helps formulators identify ingredients that have potential environmental and human health benefits and pass the U.S. EPA's Design for the Environment Screens for Safer Chemical Ingredients. It also helps chemical manufacturers showcase their chemicals with superior environmental and human health profiles. www.cleangredients.org

Design for Environment

To apply design for the environment methods, states and businesses need to be able to quickly assess, categorize, prioritize, and act on chemicals using prevention measures. Information about chemical hazards, exposures and risks is necessary before this action can occur. Many tools are available to assist states and businesses in this process.

Two recent reports present information about many such tools:

- A February 2008 report by the Center for Sustainable Production *Options for State Chemicals Policy Reform: A Resource Guide, contains Module 3: Assessment and Prioritization of Chemicals: Policy Options for States and the Federal Government,* which discusses how states can rapidly screen chemicals and rank them for hazards and risks. It also describes how governments can best decide where to focus their risk management efforts. This module includes examples of many tools for screening, assessing/prioritizing, and decision-making about chemicals and processes. http://www.sustainableproduction.org/ (Click on *Publications*, then *Chemicals Policy*).

- A 2005 report by the Toxics Use Reduction Institute at the University of Massachusetts Lowell, *Alternatives Assessment for Toxics Use Reduction: A Survey of Methods and Tools Methods and Policy Report No. 23,* focuses on nine tools for alternatives assessment of chemicals that have been developed by government and private organizations in the United States and Europe. This report also includes a summary of over 100 various methods and tools that were available as of 2004, ranging from full life cycle assessment to specific parameter assessment tools. www.turi.org/library/turi_publications/toxics_use_reduction_policy_analysis/alternatives_assessment_for_toxics_use_reduction_2005

EPA has developed an extensive array of tools to assist in chemical prioritization and assessment. Many of them are available on these EPA websites: www.epa.gov/oppt/tools/dsalpha.htm and www.epa.gov/epahome/Data.html/. See Appendix B for a listing and description of some of the EPA tools addressing chemical toxicity, exposure assessment, and hazard and risk assessment.

EPA's website (www.epa.gov/dfe/) Design for Environment section also provides numerous fact sheets, case studies, Cleaner Technology Substitute Assessments, and life cycle assessments demonstrating alternatives assessment methodologies for specific processes and/or specific chemicals.

A Sampling of a Few of the Tools in the Toolbox

Dutch QuickScan

The Dutch Ministry of Housing, Spatial Planning and the Environment developed the Quick Scan method to prioritize the management and evaluation of about 100,000 substances. Using existing data, criteria, and decision-making rules to evaluate substances, the method assigns a substance one of five different categories of concern. Both "hard" (animal testing results) and "soft" (scientific literature, expert judgment, and structure-activity models) data are used in the evaluation. The Quick Scan considers risks to workers, consumers, and the environment, and is completed by industry for all substances produced, traded, or used in the Netherlands. www.vrom.nl/pagina.html?id=37626 (see Progress Report, 2001).

Kemi PRIO

The Swedish Chemicals Agency's PRIO is a web-based tool that facilitates the assessment of health and environmental risks of chemicals so that environmental managers, purchasers, and product developers can identify the need for risk reduction. PRIO also provides a guide for decision-making that can be used in setting risk-reduction priorities. The PRIO database contains chemicals identified as being of high concern by the government (phase-out or risk reduction). It allows users to search for substances, obtain information on properties, identify substances contained in product types, and obtain help in developing support for product development. www.kemi.se/templates/PRIOEngframes___4144.aspx

Green Screen

Clean Production Action's Green Screen for Safer Chemicals is a comparative hazard assessment method designed to inform decision-making by businesses, governments, and individuals concerned with the risks posed by chemicals and to advance the development of green chemistry. The Green Screen defines four benchmarks on the path to safer chemicals, with each benchmark defining a progressively safer chemical:

1. Avoid—chemical of high concern.
2. Use but search for safer substitutes.
3. Use but still opportunity for improvement.
4. Prefer—safer chemical.

Each benchmark includes a set of hazard criteria that a chemical, along with its known and predicted breakdown products and metabolites, must pass. All of the hazard and benchmark criteria developed for the Green Screen are based on government and other precedents for classification. www.cleanproduction.org/Greenscreen.php

PBT Profiler

EPA's PBT Profiler, a web-based evaluation tool, estimates environmental persistence (P), bioconcentration potential (B), and aquatic toxicity (T) of discrete chemicals based on their molecular structure. The user enters a chemical using the Chemical Abstract Service Registry Number (CASRN). If the chemical is in the accompanying database of more than 100,000 chemicals, the structure is retrieved and entered into the model. A drawing program is also available so that the user can draw and enter the structure. The PBT Profiler may be valuable for those developing new chemicals or considering the use of new chemicals. www.pbtprofiler.net/

Appendix A

North American Eco-logo Certification and Recognition Protocols

Three major certification and recognition programs exist in the North American market to allow for third-party certification and U.S. EPA recognition. These programs are available to manufacturers and suppliers who wish to differentiate their products as "green" in the marketplace.

EcoLogo

EcoLogo is a North American eco-labeling program initially launched by the Canadian federal government in 1988. The EcoLogo program helps identify environmentally preferable ("Green") goods and services. EcoLogo certification identifies environmental leadership, high quality products, and proven environmental claims. EcoLogo meets ISO 14024 requirements, and the logo itself is internationally recognized. Currently the EcoLogo program is managed by TerraChoice Environmental Marketing, Inc. Products meeting the criteria of the EcoLogo program will normally carry the EcoLogo symbol depicting three doves intertwined with three maple leaves. www.ecologo.org/en/

Green SealTM

Green Seal, founded in 1989, is an independent non-profit organization dedicated to safeguarding the environment and transforming the marketplace by promoting the manufacture, purchase, and use of environmentally responsible products and services. The Green Seal program embodies a number of environmental and performance standards for a diverse landscape of products. Well-known standards for institutional cleaning products include the GS-34 Standard for Degreasers, the GS-37 Standard for Industrial & Institutional Cleaners, and the GS-40 Standard for Industrial & Institutional Floor Care Products. Products certified as Green Seal usually carry the distinctive Green Seal checkmark logo. www.greenseal.org/

EPA's DfE Formulator Program

The DfE Formulator Program, situated in the U.S. EPA's Office of Pollution Prevention and Toxics (OPPT), is a rigorous, science-based program that encourages partners to reformulate products to be environmentally safer, cost competitive, and effective. Products meeting the DfE criteria are allowed to display the distinctive DfE globe logo on labels and literature. That DfE logo means that each ingredient in the product has been screened for potential human health and environmental effects and that – based on current available information, predictive models, and expert judgment – the product contains only those ingredients that pose the least concern among chemicals in their class.

The DfE Formulator Program is distinct from other product recognition or ecolabeling programs because of two defining characteristics: its assessment methodology and its use of a technical review team with many years of experience in assessing chemical hazards, applying predictive tools, and identifying safer substitutes for chemicals of concern. The National Sanitation Foundation (NSF), located in Ann Arbor, Michigan, and ToxServices based in Washington, DC also assist the DfE Program as third-party reviewers of the toxicological aspects of products submitted for DfE recognition.

The DfE Screens for Safer Ingredients, have enhanced the transparency of the DfE Program. Developed in partnership with a broad group of stakeholders, the screens allow the program to evaluate each formulation ingredient within its functional class based on critical health and environmental endpoints. In this way, ingredients can be viewed as part of a continuum of improved or safer ingredient choices. In establishing thresholds for green ingredients, the screens delineate the safer or low-concern end of the spectrum, guiding and ensuring best-in-class ingredients for DfE-recognized products. (For more information on the DfE Screens see www.epa.gov/dfe/pubs/projects/gfcp/index.htm.)

The DfE Formulator Program partners with manufacturers of chemically blended products, helping them bring to market a wide range of safer products, from all-purpose cleaners and conversion coatings that do not use Chrome 6, to holding tank treatments and zinc-free floor finishes.

The Formulator Program has had especially strong participation from the cleaning product sector and counts among its partners many large, small, and medium-sized companies. Over the past year, interest has intensified in the consumer products area, driven by corporate sustainability efforts, including Home Depot's Eco Options program and Wal-Mart's on-going challenge to their suppliers to use safer ingredients in their products. www.epa.gov/dfe/pubs/projects/formulat/index.htm

Appendix B

US EPA Tools for Chemical Toxicity, Exposure Assessment, Hazard and Risk Assessment

Chemical Toxicity Data

IRIS Database - IRIS is a database of human health effects that may result from exposure to various substances found in the environment. IRIS was initially developed for EPA staff in response to a growing demand for consistent information on chemical substances for use in risk assessments, decision-making, and regulatory activities. www.epa.gov/iris/

OncoLogic is a desktop computer program that evaluates the likelihood that a chemical may cause cancer. www.epa.gov/oppt/newchems/tools/oncologic.htm

Scorecard - The Scorecard Database provides information on chemical releases, risk prioritization of substances, and other relevant information for chemicals and facilities. www.scorecard.org

Triage Database - Triage is a searchable database of scientific studies on the health and environmental effects of toxic chemicals related to Section 8(e) of the Toxic Substances Control Act (TSCA). www.epa.gov/8e_triag/

TSCATS - (Toxic Substances Control Act Test Submissions) is an online index to unpublished, non-confidential studies covering chemical testing results and adverse effects of chemicals on health and ecological systems. The studies are submitted by U.S. industry to EPA under several sections of TSCA. There are four types of documents in the database: Section 4 chemical testing results, Section 8(d) health and safety studies, Section 8(e) substantial risk of injury to health or the environment notices, and voluntary documents submitted to EPA known as a *For Your Information* (FYI) notice. www.rtknet.org/tsc/

Exposure Assessment Tools

The EPA Office of Pollution Prevention and Toxics (OPPT) has developed several exposure assessment methods, databases, and predictive models to help in evaluating:

- What happens to chemicals when they are used and released to the environment.
- How workers, the general public, consumers and the aquatic ecosystems may be exposed to chemicals.

See www.epa.gov/oppt/exposure/ for the list of tools and descriptions of them.

These tools may be helpful when appropriate monitoring data are not available or need to be supplemented, when considering potential exposure in the design and selection of products and processes and when evaluating pollution prevention opportunities. The

results of an exposure assessment are generally combined with a hazard assessment (potential for a chemical to cause adverse health or environmental effects).

Hazard and Risk Assessment Tools

ECOSAR (Ecological Structure Activity Relationships) is a personal computer software program used to estimate the toxicity of chemicals used in industry and discharged into water. The program predicts the toxicity of industrial chemicals to aquatic organisms such as fish, invertebrates, and algae by using Structure Activity Relationships (SARs). The program estimates a chemical's acute (short-term) toxicity and, when available, chronic (long-term or delayed) toxicity. www.epa.gov/oppt/newchems/tools/21ecosar.htm

The **High Production Volume Information System** (HPVIS) provides complete and easy access to technical health and environmental effect information on chemicals that are manufactured in exceptionally large amounts. Information in this database is submitted through EPA's High Production Volume (HPV) Challenge Program. HPVIS allows users to search for summary information, test plans, and new data on high production volume chemicals as they are developed. www.epa.gov/hpvis/index.html

PBT Profiler - an evaluation tool that estimates environmental persistence (P), bioconcentration potential (B), and aquatic toxicity (T) of discrete chemicals based on their molecular structure. The user enters a chemical using the Chemical Abstract Service Registry Number (CASRN). If the chemical is in the accompanying database of more than 100,000 chemicals, the structure is retrieved and entered into the model. A drawing program is also available so that the user can draw and enter the structure or the structure can be entered as a line notation using the Simplified Molecular Input Line Entry System (SMILES). The PBT Profiler is a web-based evaluation tool that may be valuable for those developing new chemicals or considering the use of new chemicals. www.pbtprofiler.net/

RSEI (Risk-Screening Environmental Indicators) is a computer-based screening tool developed by EPA that analyzes risk factors to put Toxics Release Inventory (TRI) release data into a chronic health context. www.epa.gov/oppt/rsei/

Appendix C

References and Resources

General Green Chemistry and Design for Environment Resources

- **American Chemical Society's Green Chemistry Institute** www.acs.org (includes information on the annual GC and Engineering Conferences and on the Pharmaceutical Roundtable www.acs.org/gcipharmaroundtable).
- **Green Chemistry and Commerce Council** www.greenchemistryandcommerce.org/home.php
- **Green Chemistry Resource Exchange** www.greenchemex.org/
- **Lowell Center for Sustainable Production** www.sustainableproduction.org/
- **U.S. Environmental Protection Agency** www.epa.gov/greenchemistry (includes link to Presidential GC Challenge Awards) and www.epa.gov/dfe/.
- **Warner Babcock Institute for Green Chemistry** www.warnerbabcock.com/

State Green Chemistry and Design for Environment Resources

- **California Green Chemistry Initiative** www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/index.cfm
- **California Department of Toxic Substances Control**, *Green Chemistry Options for the State of California* - includes extensive list of resources www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/SAP_Report.pdf
- **California, Maine and Washington laws** on the use of flame retardant polybrominated diphenyl ethers– search the State Legislation database at www.chemicalspolicy.org/
- **Michigan Green Chemistry Program** - www.michigan.gov/deq/0,1607,7-135-3585_49005---,00.html
- **Michigan Green Chemistry Action Plan** – Michigan Department of Environmental Quality and the Lowell Center for Sustainable Development, *Advancing Green Chemistry: An Action Plan for Michigan Green Chemistry Research, Development and Education* www.michigan.gov/documents/deq/deq-ess-p2-chemistry-actionplan_236382_7.pdf
- **New York Environmentally Preferable Purchasing Guide** - www.nyc.gov/html/nycwasteless/downloads/pdf/eppmanual.pdf
- **New York Empire Development Fund** - www.empire.state.ny.us/Manufacturing_&_Environment/Environment/pollution_prevention.asp
- **New York Pollution Prevention Institute** - www.nysp2i.rit.edu/

- **Washington Environmentally Preferable Purchasing Program** - www.ga.wa.gov/PCA/SL/ManualsGuidelines/Manuals/EPP-Manual.pdf#Page=7
- **Washington Polybrominated Diphenyl Ether Chemical Action Plan** - www.ecy.wa.gov/biblio/0507048.html
- **Washington Mercury Chemical Action Plan** - www.ecy.wa.gov/biblio/0303001.html
- **Washington State Green Economy Framework** - www.ecy.wa.gov/climatechange/greeneconomy_framework.htm

Educational Institution Green Chemistry and Design for Environment Resources

- **Beyond Benign** – www.beyondbenign.org
- **EPA Green Engineering** - www.epa.gov/opptintr/greenengineering/
- **Gordon Research Conference** – Green Chemistry at Bates College www.grc.org/programs.aspx?year=2008&program=green
- **Green Chemistry Education Network** (University of Oregon) - www.gcednet.org/
- **Green Chemistry at the University of Oregon** - www.uoregon.edu/~hutchlab/greenchem/
- **New England Green Chemistry Consortium** - http://chemistry.umeche.maine.edu/Green.html
- **Northern Essex Community College Technology Center's Green Chemistry Business Summit** www.rsc.org/chemsoc/gcn/pdf/GCBSSummaryNotes.pdf
- **University of Oregon's Greener Educational Materials for Chemists** - http://greenchem.uoregon.edu/gems.html

Additional Green Chemistry and Design for Environment Resources

- **Canadian Domestic Substances List Categorization** - www.ec.gc.ca/ceparegistry/subs_list/dsl/s1.cfm
- **EPA Environmentally Preferable Purchasing** - www.epa.gov/opptintr/epp/
- **France reduced-interest loans** http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/205&format

CHANGE
Californians for a Healthy & Green Economy

April 23, 2009

Maziar Movassaghi
Director
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Green Chemistry Initiative, AB 1879, SB 509

Dear Director Movassaghi:

We write on behalf of CHANGE, Californians for a Healthy and Green Economy. CHANGE is a broad-based coalition of about 35 environmental and environmental justice groups, health organizations, labor advocates, community based groups, parent organizations, and others who seek to fundamentally transform how chemicals are managed in order to protect our workers, children, public health, environment, and the economy.

First, we congratulate you on the conduct of the Green Chemistry Initiative and the public workshops in during the last few months, after completion of the Green Chemistry Initiative Final Report last December. We have appreciated the many opportunities you have provided during this Initiative for us to express our views on chemicals policy reform.

At the April 21, 2009 Workshop in Berkeley DTSC proposed a "Draft Straw Proposal" for the implementation of AB 1879 and SB 509. While members of CHANGE have regularly attended the DTSC public workshops including the most recent one in Berkeley and have offered comments during those workshops, we would like to offer these written comments on the "Draft Straw Proposal." We also stand ready to assist the Department in developing actual regulatory language once the structure and objectives of this Proposal are more clearly decided. In the meantime, please consider these comments on DTSC's Proposal.

I. SECTION 3 PROCESS TO IDENTIFY CHEMICALS OF CONCERN

a. Any chemical that may threaten human health or the environment should be considered a chemical of concern

Under AB 1879 and SB 509, DTSC is intended to develop a comprehensive chemicals policy, and any such policy should respond to any and all threats posed by chemicals in commerce to human health or the environment. We believe that a chemical posing any kind of threat to human health or the environment, either alone or in combination with other factors, should be considered a chemical of concern. There is no reason for the regulations to exclude any particular kind of hazard from potential regulation by the State.

We also believe that the threshold of evidence required for determining that a chemical may pose a threat should be low enough to constitute an early warning of harm. That is, a small amount of evidence or even equivocal evidence should be sufficient for a chemical to be designated as being of concern and therefore to potentially warrant further scrutiny.

This means that many of the chemicals in commerce will become designated chemicals of concern. We encourage this. Because these chemicals will be acted on only if prioritized, many chemicals of concern will not be acted on by DTSC. Nevertheless, the mere designation of chemicals as being of concern should motivate consumers and industry to avoid them in favor of those that are not. This would clearly be warranted and would further the market-oriented goals of the program.

b. DTSC should not limit the regulations to conventional consumer products

SB 509 and AB 1879 have been argued by industry representatives to be limited to consumer products (with some specific exceptions set forth in Section 25251(e)). We believe such a limitation would be unwarranted. The definition provided by the statute clearly includes all chemicals that are bought by any person for any purpose. Thus, essentially all chemicals in commerce should be subject to a new, comprehensive chemicals policy.

This is important because many chemicals are purchased by industry for use in manufacturing or otherwise in the workplace, and can harm workers and/or the environment without being what are typically considered consumer products. Workers in particular often bear the brunt of chemical exposures because of their close proximity to large volumes of chemicals in the workplace. They also often inadvertently function as a vehicle for exposure of family members and neighbors to chemicals they are exposed to in the workplace. The current frequent discrepancies between many workplace standards and environmental or other standards are not justifiable and are improper. Accordingly, we urge DTSC to take workplace exposures seriously and to consider workers as a potentially highly exposed population.

Products containing nano materials, though they seem to be evading TSCA, are specifically included within the ambit of the legislation. Specific classes of chemicals such as pharmaceuticals and pesticides should be excluded only if they are already subject to adequate regulatory programs.

c. DTSC should establish a "no data, no market" requirement by establishing a required data set to identify chemicals of concern

As the Green Chemistry reports by U.C. Berkeley have demonstrated, many chemicals on the market are likely to be hazardous even though we have little or no chemical safety information about them. Such chemicals present hazards to human health and the environment even though the hazards are unrecognized. Indeed, one might say they are of greater concern than chemicals for which we have hazard data because people have no way of avoiding hazards that they cannot recognize. As DTSC begins to take action on known hazardous chemicals under this Green Chemistry Initiative, there is a high likelihood that such chemicals will be replaced by alternatives posing unrecognized hazards, thereby resulting in little or no real improvement in public health and the environment. Such perverse consequences should be avoided by a comprehensive chemicals policy.

Accordingly, DTSC should seek to identify all chemicals in commerce that are of concern, whether that concern is recognized today or not. DTSC should specify a required data set that must be provided by industry to the public for all chemicals in commerce, both new and existing. The information must be sufficient to permit a reasonable evaluation of the safety of the chemical for human health and the environment, including not just hazard information, but also product use (ingredient) and exposure information. The design of the required data set may be coordinated with, but not limited to, other chemical data collection programs, including REACH. Such required data sets should be provided for all chemicals in commerce within about ten years. DTSC should be able to request further information beyond the required data set if it would help the State in evaluating the chemical or as we learn more about chemical impacts on the environment.

There must be a regulatory penalty when the required data set is absent in order to motivate industry to produce the required information. At the very least, chemicals with insufficient data should be designated chemicals of concern and subject to some kind of regulatory response. We believe the appropriate response is that a mandatory data set should be required both for new chemicals before they are introduced into commerce and for all existing chemicals in commerce by a date certain as a condition for being permitted on the market. If it is not provided, chemicals should not have access to the market.

Also, industry should also be required to produce all health and safety information in its possession even if it is not part of the required data set. A required data set could be coordinated with and provide a basis for requests for further information under HSC § 25253(b).

Finally, DTSC should pay attention to the problem of identifying suitable information requirements for nanomaterials. These new materials clearly require different kinds of information to assess their impacts than traditional chemicals.

d. Trade secret protection should not be given to any information relating to the safety of products, including hazard data and product ingredient information

AB 1879 adds new Section 25257 of the Health and Safety Code relating to trade secret information. Despite Section 25257(f), this section arguably may permit submitters to claim trade

secret designation for some kinds of health and safety information as well as product ingredient information.

We believe that no information relating to the environmental health impacts of a chemical of concern should be withheld from the public through trade secret designation. This includes information about both the hazard properties of chemicals and the ingredients in products. Even if such information has competitive value, the public's need for that information in order to evaluate whether a chemical is a chemical of concern, to review the alternatives analyses done under these laws, and to choose safer chemicals and products, outweighs that competitive interest. The problem with trade secret designation for any information relating to the environmental health impacts of a product, including identification and amounts of its constituent ingredients, is that all evaluations of chemicals and products based on that information will also be removed from the public domain. In that event, all decisions about chemicals would be driven into a process in which only government and the affected industry can participate.

The public should have complete access to all decisions about chemicals of concern used in products, including public oversight of listings of chemicals of concern, regulatory decisions and alternatives analyses. Public access is required if this new chemicals policy expects to harness the ability of the consumer and industrial markets to respond to chemical safety information. These goals can only be accomplished if there is complete transparency for all chemical safety and product ingredient information for chemicals of concern.

Accordingly, new HSC Section 25257 should be implemented as follows. No information relating to the health and safety of a chemical, including the chemical's identity and product ingredient information needed to assess safety, should be granted trade secret protection. A party seeking trade secret designation for any information should assert each basis for such designation in writing when the information is submitted to DTSC. DTSC should make a case-by-case determination as to whether the party has established that such designation is appropriate. The submitting party should provide DTSC with a redacted, public version of each filing in order to relieve DTSC of the burden of preparing such documents. Each grant of trade secret protection should be time limited, subject to renewal upon application by the submitter. The public should be notified of all trade secret designations approved by DTSC and provided sufficient information to challenge that designation.

Two ideas for accommodating the interests of industry in trade secret information have been suggested. One is to disclose only ranges of product ingredient concentrations. We do not support use of thresholds below which no information need be reported at all. But a reported range might be workable if the regulatory assumption that follows were that the maximum concentration (or most hazardous concentration) in the range were used in doing alternatives analyses and fashioning a regulatory response. A second possibility would be to find some way to recognize the value of trade secret information by granting some preferential regulatory use to those industries that produce the information, means of obtaining compensation from other industries or other such provisions. Once DTSC clearly determines that information relating to the environmental health impacts of a chemical of concern will not be designated as a trade secret, we would gladly participate in a discussion about these kinds of accommodations.

e. Animal tests should be phased out

In designing data requirements or in requesting chemical toxicity data about any chemical or alternative, DTSC should recognize that there is profound ethical concern with the continued use of animal tests. A growing body of alternative, faster, more reliable techniques is being developed. Animal tests are also expensive and time consuming. All these reasons have led the National Research Council and others to recommend replacing animal toxicity tests with better methods. They also led the EU to incorporate into REACH numerous provisions designed specifically to keep animal testing to a minimum. Accordingly, DTSC regulations should ensure that animal testing be kept to a minimum, that duplicative animal testing be prevented, and that animal testing will ultimately be phased out completely.

f. Providing updated information on uses, productions volumes and patterns, and health and environmental impacts

The Draft Straw Proposal, on page 5 at the end of Section 3, sets forth specific information that should regularly be provided by industry for newly introduced chemicals as they become incorporated into commerce. We believe this same data should be provided for existing chemicals. 92% of the 3,000 High Production Volume chemicals in commerce today were in commerce in 1979, and their uses have continued to proliferate and grow since then. Accordingly, the need to continually evaluate chemicals as they spread throughout commerce relates not just to new chemicals but to existing ones as well.

g. Conducting and paying for assessments and evaluations

Both the data and the various analyses that are produced under AB 1879 and SB 509 must be reliable and credible. We also believe that the financial burden for producing the data and analyses should be borne by industry. We recognize that there are advantages in having industry create chemical information and perform analyses, but we also recognize the inevitable impact of self-interest on the conduct of these activities. DTSC should collect funds from industry to have independent third parties perform these activities under supervision of DTSC. DTSC should develop mechanisms designed to ensure that industry bears the financial costs of data production and assessment, that the assessment process is transparent, and that government and the public have oversight and review capability to ensure the credibility and reliability of chemicals management.

II. SECTION IV PROCESS TO PRIORITIZE CHEMICALS OF CONCERN

a. Categories of chemicals of concern that should considered high priority for stronger regulatory responses

Several classes of chemicals are of higher concern than others, and DTSC should prioritize these for rapid review, restriction and possibly elimination. We recognize that the following classes of chemicals should be defined more precisely, and we are prepared to assist the Department in developing such definitions.

Some chemicals of concern that DTSC should prioritize because of their hazardous nature include:

(1) Carcinogens, mutagens and reproductive and developmental toxins (CMR's) are of such high priority because they cause devastating diseases and often have the capacity to affect future generations;

(2) Persistent, bioaccumulative and toxic chemicals (PBT's) are of high priority because they accumulate in the environment, persist, often for long periods of time, and often concentrate in the environment and in species higher on the food chain, including humans;

(3) Very persistent, very bioaccumulative chemicals (vPvB's) are of concern even if not known to be toxic because of their persistence and tendency to concentrate in the environment and in people; and

(4) Other hazardous properties of equivalent concern include endocrine disruptors.

Some chemicals of concern that DTSC should prioritize because of the likelihood that many people are exposed to them, including:

(5) Chemicals sold or used in high volumes in the state;

(6) Chemicals that are widespread in the environment or chemicals (or their metabolites) that are found in tissues of people in the State through biomonitoring; and

(7) Chemicals that vulnerable subpopulations are likely to be exposed to, including workers, pregnant women and children.

We agree with DTSC's suggestion that any chemical for which an adverse environmental impact is detected should be prioritized.

We also agree that any chemical for which a minimum data set is not available should be prioritized for provision of the missing data or phase out.

III. SECTION 5 PROCESS TO EVALUATE POTENTIAL ALTERNATIVES

a. Avoidance of paralysis by analysis, use of life-cycle "thinking

Conflicting data, lack of information and competing priorities can all lead to unduly lengthy analytical processes. AB 1879 refers in several places to the use of "life-cycle analysis" in reaching chemical decisions. As both the GCI Final Report and the May 2008 Science Advisory Panel's Report made clear however, many of the important concepts and values implicit in considering the full life-cycle impacts of chemical production, use and disposal can be considered more efficiently under the

rubric of "life-cycle thinking." See May 2008 SAP Report at pp. 5-6; GCI Final Report at pp. 13-14, 30-32, 34-36. We urge DTSC to follow this insight and take a life-cycle thinking approach to implementing AB 1879, and to establish specific, short time frames for conducting them.

b. Alternatives analyses and life-cycle assessments should be broad in scope

All potential adverse effects on both human health, including workers, and the environment should be considered. Long term effects and cumulative effects should be considered. Economic impacts tend to preference the existing economic actors and this should be avoided, but if economic impacts are to be considered, then entire life cycle costs must be considered.

c. New chemicals should be assessed as well as chemicals already on the market

New chemicals should be assessed before marketing based on a required data set. Any data gaps should be specifically identified and action taken to close them. Otherwise, industry will continue to introduce new chemicals of concern, with their hazards are unrecognized, into the market.

d. Alternatives analyses should be made public

The alternatives analyses should be made public, including all information that is necessary to the analyses. Trade secrecy claims should be strictly limited so as not to prevent full public access to the analyses. There should be opportunity for the public and industry to comment on alternatives assessments and an obligation for those conducting them to respond and incorporate comments in revised assessments.

e. Non-chemical solutions

Options for replacing a chemical with a non-chemical solution should be part of alternatives analyses. Such options may include change in feedstock, change in production or change in basic material.

f. Safer alternatives may need to be regulated to protect human health and the environment

If a safer alternative is identified to a chemical of concern, but that safer alternative still presents a hazard to human health or the environment, then regulatory steps should be taken to restrict and condition any permitted uses of the alternative as well. Just being a safer alternative should not guarantee access to the market for a chemical of concern.

g. Alternatives assessments should be paid for but not be conducted by industry

Alternatives assessments must be credible and reliable if the public is to rely on them. They should be paid for by industry, but conducted by an independent third party with oversight by Cal/EPA to ensure quality control. We recommend a fund that product and chemical manufacturers pay into that can be used with DTSC oversight to fund assessments. DTSC should exert strong oversight over all assessments.

h. Alternatives assessments should be revisited periodically

It is important for alternatives assessments of prioritized chemicals of concern to be revisited and revised if necessary. This type of continuous process is critical to open up opportunities for new, safer chemicals to be recognized and be able to penetrate the market.

i. There must be a duty to investigate both whether products contain chemicals of concern and the properties of those chemicals

The Draft Straw Proposal provides that responsibility for performing alternatives assessments (or providing information to a third party assessor under our recommendation) will fall on the party responsible for introducing the product into commerce in California. This will often be retailers or product assemblers who have not themselves manufactured the products or constituent parts and who therefore are unlikely to know the composition of the products they introduce into commerce. These parties must be placed under a specific duty to investigate and demand information from their suppliers, to certify they have taken the required steps and provide the results. Unless all elements of the supply chain, including elements from beyond the state, are required to divulge the contents of products eventually sold in the state, effective alternative analyses will not be possible.

IV. SECTION 6 REGULATORY RESPONSES

a. DTSC should develop a mandatory regulatory program

DTSC should develop, implement, and enforce a program of regulatory responses that are mandatory, and not just voluntary. Voluntary programs have proved to be unable to protect public health and the environment.

b. DTSC should take immediate action to restrict or eliminate the use of high priority chemicals of concern independently of any alternatives analysis

High priority chemicals of concern, as we have defined them above, should be substantially restricted or removed from the market based on presenting a threat to human health and the environment, regardless of whether there is a safer alternative and independently of the program of alternatives analyses.

AB 1879 and SB 509 refer to several potential bases for regulating chemicals, including alternatives analysis (see HRC Section 25253(a)(2)) and "determining how best to limit exposure or reduce the level of hazard posed by a chemical of concern" (see HRC Section 25253(a)(1)). We interpret this to mean that if a safer alternative exists to a particular chemical, DTSC must take steps to restrict or phase out use of that chemical in order to protect environmental health and to promote use of the alternative. But we believe it also means that even where there is no safer alternative, industry should not be permitted to place or maintain a chemical on the market unless it can demonstrate with a reasonable certainty that the chemical is safe.

c. High priority chemicals that are found in cord-blood should be rapidly phased out

We believe that high priority chemicals of concern, such as CMR's, PBT's and vPvB's, that are found in human cord blood present such an unreasonable threat that they should be immediately phased out of commerce.

d. High priority chemicals of concern should be required to pass a safety test

Though an open-ended requirement for proof of safety would admittedly be difficult to satisfy, we believe that a safety test can and should be satisfied with respect to a data set that is required by the state pursuant to mandatory data requirements (plus any additional information that is requested by the state or otherwise becomes available). Where the state determines that a manufacturer has failed to make this showing, either because of the results of the data, or by failing to fulfill mandatory data requirements, chemicals should not be permitted to remain on or be introduced into the market.

We believe this safety standard should focus on whether the chemical presents an intrinsic hazard, and not on risk assessment or on balancing safety with economic or other countervailing considerations. Specifically, a legal test structured like that of the federal Toxic Substances Control Act, which permits use of monetized cost benefit analysis in which economic factors are weighed against human health or the environment, should not be part of any regulatory program under which the state seeks to better manage chemical hazards.

Moreover, in determining whether manufacturers have demonstrated the safety of their products, the state should ensure that manufacturers account for the importance of low doses, background exposures, synergistic effects, and the timing of exposures during the life cycle; account for the effects of cumulative exposures and differences in genetic responses to chemical exposure; and evaluate the hazards to the most vulnerable populations, most fragile ecosystems, and most susceptible life stages.

e. Industry should bear the burden of proof

The Draft Straw Proposal is not clear about who bears the burden of proof before regulatory action can be taken. For example, Sections (4) "Restrictions" and (5) "Prohibitions" both indicate that regulatory responses will be taken if "the data indicates a risk" or "data . . . indicates an impact." The question is, who has to make establish these facts? If DTSC is not careful, it will end up in the same straightjacket that EPA is now in under TSCA – EPA carries the burden of proof to show a chemical meets the required legal tests. As a consequence, all data gaps and uncertainties in the data militate against regulation, rather than for it.

In this case, high priority chemicals of concern should not be presumed safe with government bearing the responsibility to demonstrate that a chemical is unsafe or has a safer alternative in order for it to be regulated. Such a legal structure undermines producer responsibility, motivates manufacturers and commercial users to resist generating public information about the safety of their products, and makes it unreasonably difficult for government to take steps necessary to protect the public and the environment.

Allocating the burden of proof to industry rather than DTSC is a critical element of creating a system that will enable DTSC to protect public health and the environment and that will encourage rather than discourage the production of information. Several models exist for placing the responsibility on industry to demonstrate the safety of their products or lack of safer alternatives. These models include the European REACH legislation for authorization of industrial chemicals and the proposed "Kids Safe Chemicals Act of 2008" in the U.S., as well as models outside the field of industrial chemicals, such as the regulation of pharmaceuticals under the Federal Food, Drug and Cosmetics Act. DTSC should build on these models in structuring its regulatory program.

For example, it may be appropriate for DTSC to make an initial determination that a chemical is a chemical of concern. Then, the regulations could require that industry must show to a reasonable certainty that a chemical of concern does not present a threat of harm to humans or the environment and that there is no safer alternative for each particular use.

d. DTSC should not be required to restrict or eliminate high priority chemicals through lengthy formal rulemaking

DTSC should be empowered to act promptly to protect human health and the environment without protracted delay. In such cases, DTSC should act by order of the Director. DTSC must avoid allowing “paralysis by analysis” to prevent timely decisions about such chemicals. In particular, lack of complete information must not be used as a justification for further delay. While we support development of complete information and thorough analyses of chemicals, we also believe that DTSC can and should make timely decisions about many chemicals known to be hazardous based on already-existing information.

e. There should be a regulatory response to the absence of a minimum data set

As we stated above, there must be a regulatory penalty when a minimum data set is absent or incomplete in order to motivate industry to produce the needed information. We believe a mandatory data set should be required for new chemicals before they are introduced into commerce and for all existing chemicals in commerce by a date certain as a condition for being permitted to remain on the market. If such data is not provided, then new chemicals should not be allowed on the market and existing chemicals should be removed from commerce.

f. Regulatory responses should be tied to certain outcomes of the alternatives assessments

If an alternatives assessment shows that there is a viable, safer alternative, DTSC should phase out the use of the chemical of concern for that particular use. If an alternatives assessment shows that there are not safer or viable alternatives, the department may then take any number of the actions listed in the legislation. In such cases, the department shall require a period of time in which the assessment should be conducted again in order to determine if viable safer alternatives exist.

g. Timelines and deadlines for assessments and regulatory decisions

AB 1879 and SB 509 do not generally specify deadlines for provision of required data, completion of alternatives assessments and safety assessments, or final promulgation of regulatory decisions. Such deadlines should be established so as to ensure that the public is provided safety information about chemicals in commerce as quickly as is reasonable, that review of the enormous number of chemicals already in commerce is completed within some reasonable time frame, and that regulatory decisions are made in a timely manner. Six to twelve months is a reasonable time for completing an alternatives assessment and a safety evaluation of a particular chemical based on currently existing data. One year is a reasonable time frame for making regulatory decisions. Three years is a reasonable time frame for providing a required data set for chemicals in commerce. Ten years is a reasonable time frame for completing review of all chemicals currently in commerce. Coordination of these deadlines with various programs that are underway internationally, such as REACH, may be reasonable in some instances.

h. The regulations should build in continuous improvement

As stated in the GCI Final Report, it is essential that any chemical evaluation process builds in mechanisms that encourage continuous improvement (see GCI Final Report at pp. 34-36). Since the knowledge base of chemical hazards, uses and alternatives will expand continually over time, DTSC should build into its regulations a process whereby decisions and recommendations may be revisited and revised based on newly arising information. Accordingly, DTSC should grant only time-limited approvals for uses of hazardous chemicals for which safer alternatives cannot be identified. The program should also require decisions to be revisited whenever material new information arises. Finally, DTSC should also consider various technology-forcing approaches that will drive continual adoption of safer alternatives as they are developed.

i. Sections (4) “Restrictions” and (5) “Prohibitions” should apply to a broader set of concerns

Section 6.5 currently provides for prohibitions when sensitive subpopulations are potentially affected. Prohibitions should also apply when industry cannot carry its burden of proof with respect to environment and human health generally, not just when sensitive subpopulations are threatened. Section 6.4 is broader than Section 6.5, but should also enable DTSC to respond to any threat to human health or the environment.

In conclusion, we support DTSC's effort to design a new, more effective regulatory program for chemicals in commerce. As the outlines of the program DTSC's program become better defined, we will participate in this process and offer specific suggestions and regulatory language to assist DTSC in this important work.

Sincerely,

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