

An Overview of the Toxic Substances Control Act (TSCA)

American Chemistry Council

TSCA 101



TSCA

- Enacted in 1976
- Gives EPA authority to
 - Review new chemicals before they are manufactured
 - Gather information on existing chemicals in commerce
 - Regulate chemicals

Chemical Safety Net

- TSCA is one of many statutes that regulate chemicals
- Other statutes cover pesticides; tobacco, nuclear material; food, drug & cosmetics; and pollutants
- TSCA's unique focus is on chemicals in commerce

Principle Provisions of TSCA

- ❖ **Section 4 - testing of existing chemicals**
- ❖ **Section 5 - screening of new chemicals or new uses of existing chemicals**
- ❖ **Section 6 - risk management**
- ❖ **Section 8 – information collection and reporting**
- Section 7 – imminent hazard
- Section 9 - relationship of TSCA to other federal laws
- Section 11 – inspections
- Section 12 - chemical export
- Section 13 - chemical import
- Section 14 – CBI
- Sections 15, 16 and 17 - prohibited acts, penalties & EPA's enforcement powers.
- Section 20 and 21 - citizen actions
- Section 26 – use of categories versus specific substances

At the beginning...

- When TSCA was first enacted, companies informed EPA which chemicals were produced at that time.
- That list of chemicals resulted in the initial TSCA inventory (1979).
 - Also referred to as “grandfathered” chemicals
- Any chemical developed and marketed AFTER 1979 has gone through New Chemical Review

NEW CHEMICAL REVIEW

TSCA Section 5

1. Company submits PMN (pre-manufacture notice)

- Chemical identity information
- Production volumes
- Intended categories of use
- Description of by-products
- Molecular formula
- Available information

2. EPA conducts initial review

3. EPA Develops Hazard Profile

- Structure Activity Team uses analogs
- Evaluates health effects, environmental effects, environmental fate
- Establishes health and environmental hazard potential

4. EPA Develops Exposure/Release Profile

NEW CHEMICAL REVIEW (con't)

5. EPA Holds Focus Meeting – Final Decision

- More testing is needed for EPA to make a decision
 - Company can produce data or withdraw PMN
- PMN allowed after additional data provided by company
- PMN allowed, but with use restrictions
- PMN allowed without restrictions
- PMN not allowed
 - Company can withdraw PMN before final decision

6. Company submits NOC (Notice of Commencement)

- New chemical added to the Inventory

Existing Chemicals – Reporting & Testing

TSCA Inventory

Section 8(a)
EPA
can collect
info
on exposure,
use,
production

Section 8(d)
EPA
can collect
info
on ongoing
or existing
studies

Section 8(c)
Companies
retain
allegations of
adverse effects
and submit
it to EPA
upon request

Section 8(e)
Companies
immediately
report
substantial
risk info
to EPA

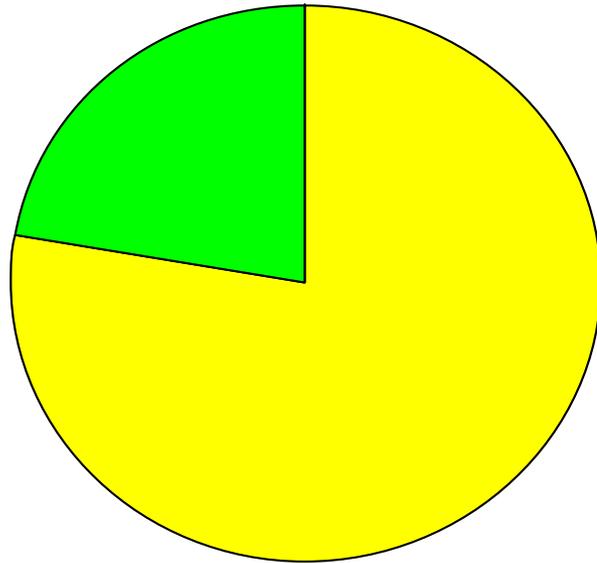
Section 8(b)
Inventory Update
Companies report
production & use
info for substance
above threshold

Section 4 test rules - manufacturers can be required to conduct tests on specified chemicals

Section 6 - EPA addresses unreasonable risks through restrictions, warning labels, recordkeeping, product bans.

TSCA Inventory

Grandfathered vs New Chemicals

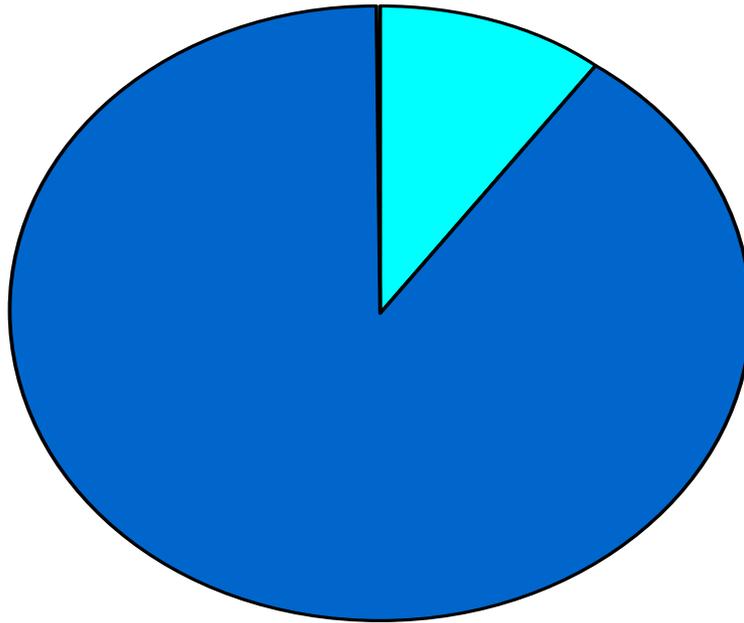


■ "Grandfathered" chemicals on TSCA Inventory	63,000
■ "New" Chemicals on TSCA Inventory (Evaluated through PMN process)	18,100

TSCA Inventory ≠ Chemical in Commerce

- The TSCA inventory is a comprehensive list of all chemicals ever allowed by EPA to be manufactured.
 - This list contains about 82,000 chemicals
 - Mix of “grandfathered” and “new” chemicals
- The chemical list reported on the Inventory Update Rule (IUR) is the best reflection of chemicals actually being used in commerce.
 - The last IUR list shows about 8,300 chemicals used in commerce or about ten percent of the total TSCA Inventory
- The remaining chemicals on the Inventory are
 - Produced in small amounts (less than 10,000 pounds annually) OR
 - Not produced at all OR
 - Inorganics (such as salts) OR
 - Polymers, which are generally viewed as low risk

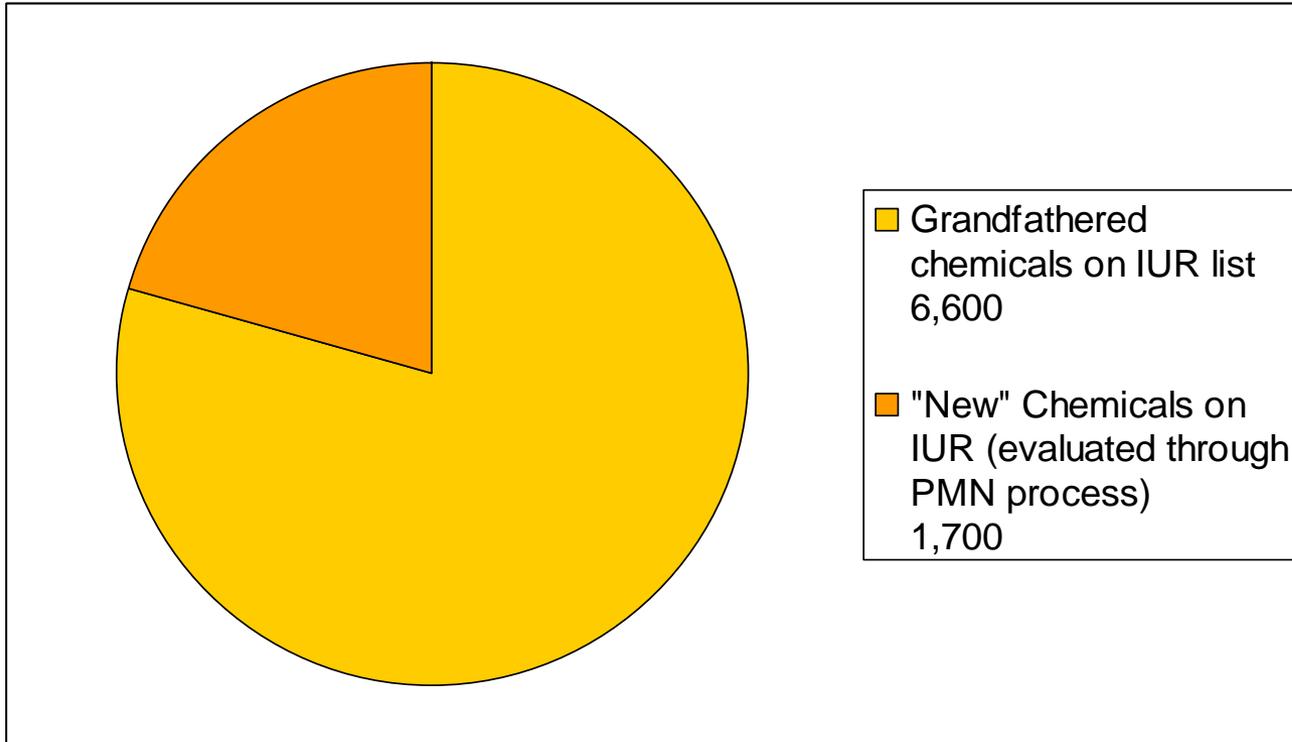
TSCA Inventory & Chemicals in Commerce



■ Chemicals in commerce
(reported on last IUR)
8,300

■ Other Inventory
chemicals (not produced
at all, produced below
IUR threshold, polymer
or inorganic)

Chemicals in Commerce Grandfathered versus New

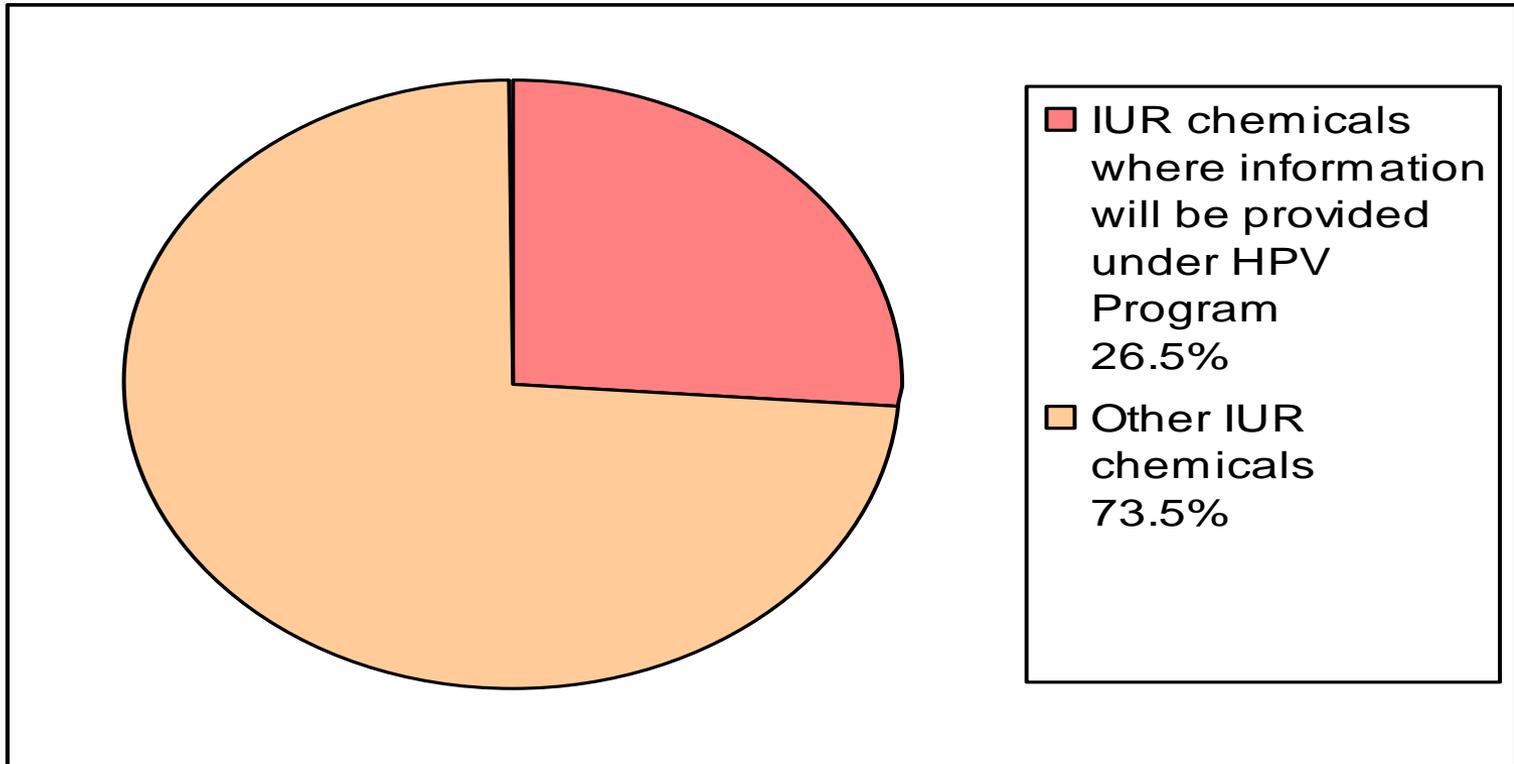


Chemicals in Commerce & HPV Program

- Industry agreed to voluntarily supply EPA with evaluation data on chemicals in commerce produced at 1 million pounds or more (aka “high production volume” or HPV chemicals)
- Under this program, information on more than 2,200 chemicals have or will be provided and made publicly available.

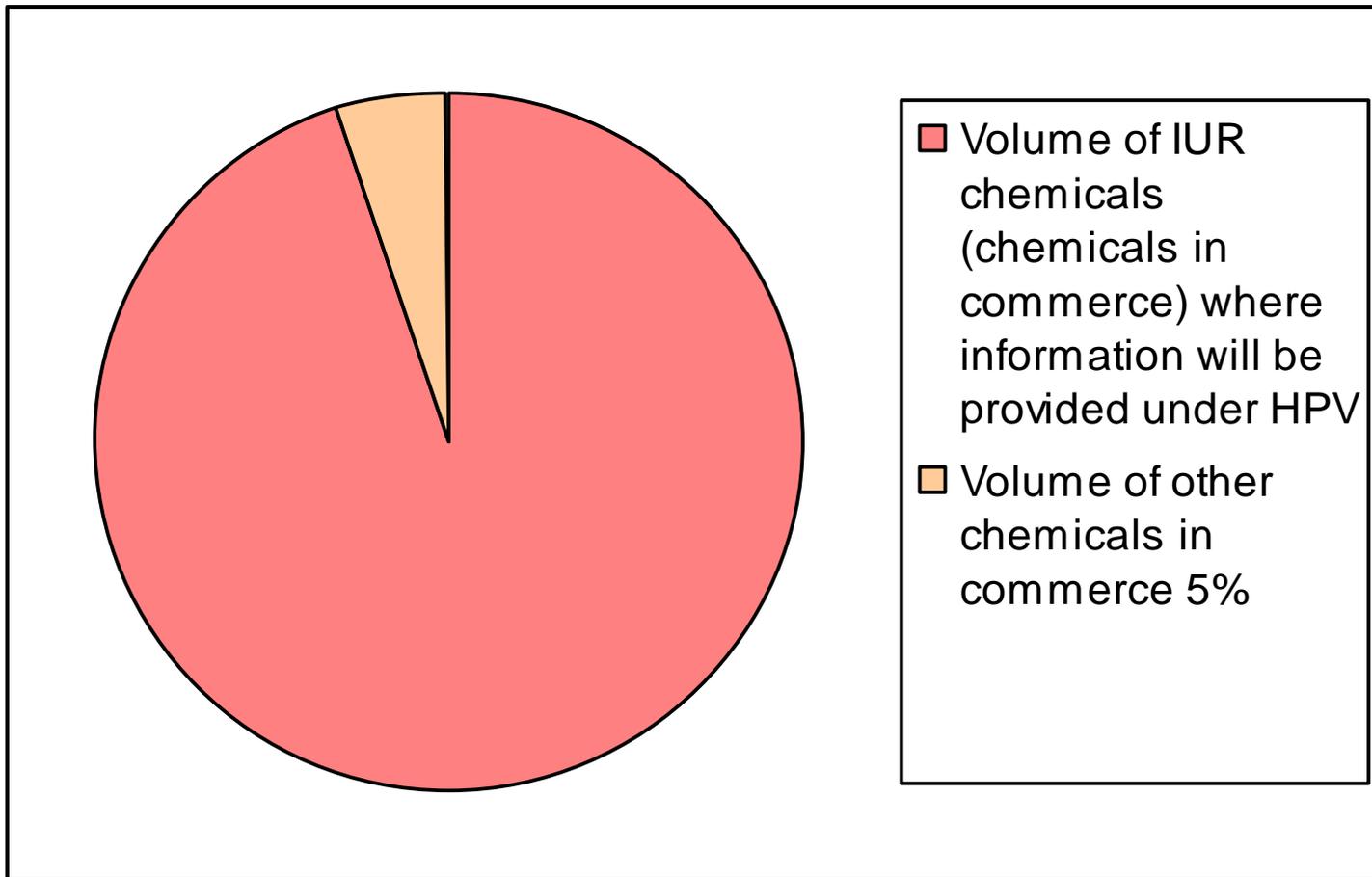
IUR & HPV – Perspective #1

Looking at individual chemicals



IUR & HPV - Perspective #2

Looking at amount (volume) of chemicals



Changes to IUR Reporting

- 2002 = most recent IUR data available
 - Reporting on organic chemicals
 - 10,000 pound reporting threshold
 - Four year reporting cycle
 - About 1,080 companies reported on about 9,000 chemicals.
- In 2003, EPA amended the IUR rules
 - Reporting on organic & inorganic
 - 25,000 reporting threshold
 - Five year reporting cycle
 - Significantly increased reporting elements to include use & exposure information
- New rules applied to 2006 IUR reports
 - Compilation of 2006 data not yet publicly available

*Let's see what you know
about TSCA*



True or False?

TSCA is the only law that is intended to enable regulation of chemicals both before and after they enter commerce.

FALSE!

Chemical industry one of the MOST regulated industries

In addition to the Toxic Substances Control Act (TSCA), we have...

- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),
- Federal Food, Drug and Cosmetics Act (FFDCA),
- Clean Air Act (CAA),
- Clean Water Act (CWA),
- Resource Conservation and Recovery Act (RCRA),
- Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA)
- Emergency Planning and Community Right-to-Know Act (EPCRA),
- Occupational Safety and Health Act (OSHA)
- Hazardous Materials Transportation Act (HMTA)
- Consumer Product Safety Act (CPSA)
- Federal Hazardous Substances Act (FHSA)
- Food Quality Protection Act (FQPA).

True or False?

TSCA was established to eliminate risks from chemicals.

FALSE

Unreasonable risk standard

Congress recognized that we do not live in a 'zero risk' world

Both the risks and benefits of chemicals need to be considered to prudently carry out the goals of the Act.

“Unreasonable risk” is the criterion for regulating or banning chemical substances under the Act.

True or False?

Companies are not required to develop specific test data for new chemicals.

TRUE

BUT a thorough evaluation of the new chemical takes place

Companies must submit:

- any available health or environmental test information
- information on the chemical identity and structure
- anticipated uses, production volume
- by-products
- human exposures
- disposal practices

EPA scientists use the information submitted to:

- Reach scientific conclusions based on chemical size & structure
- Identify structural analogs and use the analog data in evaluation
- Conduct computer modeling
 - If the above not sufficient, EPA will require testing

True or False?

The TSCA system discourages US companies' innovations in green chemistry.

FALSE

US System More Innovative

Compared to Europe, US industry has

- Higher economic performance
- Higher R&D productivity
- Higher patent productivity
- Higher polymer patent
- Higher numbers of new chemical notifications.

TSCA allows US companies to remain innovative while still appropriately evaluating the new chemicals for risk.

True or False?

EPA has required testing for about 200 existing chemicals since the agency began reviewing chemicals in 1979.

TRUE

But it's a trick question!

Testing EXISTING chemicals done under Section 4

- EPA issues Section 4 test rule OR
- EPA and companies work together under an enforceable consent agreement (or ECA)

Since TSCA was enacted, data on approximately 200 chemicals have been developed through Section 4 or ECAs.

BUT.....

Testing also done as part of NEW CHEMICAL review

- 300+ chemicals tested as part of the new chemical review process
- Remember – EPA can require testing if needed during PMN review

Work also done under voluntary programs

- HPV Chemical Challenge program
 - 300+ companies, 100 consortia
 - Hazard screening data sets have or will be completed on 2,200+ chemicals
- Voluntary Children's Chemical Evaluation Program (VCCEP)
 - 35 companies, 10 consortia
 - 20 chemicals
- Extended HPV program
 - Numbers still coming in, but at least 230 committed thus far

TSCA unique in allowing innovative approaches to gathering information needed for chemical risk management.

True or False?

EPA has issued regulations to ban or limit production or restrict the use of only five products.

FALSE

Beyond Section 6...

It's true that only five substances have been restricted under TSCA Section 6

BUT - over 1,000 substances are restricted under Section 5

- EXAMPLE: A chemical does not show unusual toxicity except to certain aquatic organisms. EPA uses Section 5 to prevent waste disposal to water or sewers, and compel disposal methods that do not present environmental risks.

AND - EPA TSCA policies impact chemical R&D work

- EPA processes & modeling software publicly available
- Policies on chemical categories of concern
- Companies regulate themselves before product submitted to EPA

In 1991, US Court of Appeals for the Fifth Circuit remanded an EPA TSCA Section 6 rule that banned asbestos. The Court ruled that EPA failed to give adequate weight to the “least burdensome” approach under Section 6(a) and that EPA did not present a stronger case for the ban of product for which no substitute was available. EPA had spent 10+ years working on the asbestos issue.

True or False?

**Because of this court case,
effective regulation of existing chemicals is
not possible.**

F A L S E

Asbestos Rule Did Not Fail Because of TSCA

It failed because EPA made rulemaking errors:

- No Notice and Opportunity to Comment on a Key Justification
- Failure to consider less burdensome alternatives
 - EPA never pursued any other risk management approaches
- Flawed Methodology/Skewed Reasoning
 - Inflated estimates of benefits
 - Failure to Consider Harm From Use of Substitutes
 - Failure to consider costs

True or False?

Information is often claimed “confidential” in TSCA submissions.

TRUE

But with very good reason!

- The issue of Confidential Business Information (CBI) cannot be taken lightly.
- Congress clearly understood the need to build in strong protections for CBI.
- TSCA compels industry to provide a wealth of sensitive data
 - Chemical identity for a new substance which may not yet have received patent protection
 - Volume produced, which would signal to competitors the potential market size for the chemical
 - Molecular weight range for a new commercially valuable polymer
 - Impurities, which can signal key information on process or precursor substances

True or False?

**Any information can be claimed as CBI
under TSCA.**

F A L S E

NOT Health and Safety Info

A company is not entitled to claim health and safety data as confidential.

Some groups argue that the general public needs access to CBI to understand potential risks, but this doesn't make much sense.

- **Presumably, the general public would be most interested in health and safety information**
 - That information cannot be claimed CBI (see above)
- Specific chemical names and chemical structures are normally claimed confidential
 - Generic descriptions of chemicals are not.
- Generic name descriptions, along with the health and safety information, is suitable for most purposes.

True or False?

There is almost no meaningful safety information on chemicals to which the public is exposed.

FALSE, FALSE, FALSE

Really, really FALSE

There is TONS of information

- Companies have conducted testing and evaluations of existing chemicals for many, many years.
 - The problem is not that the information doesn't exist.
 - It's that, until recently, it has not been publicly available.

Why wouldn't information be publicly available?

- In the old days....
 - Public databases derived from scientific journal articles
 - Journals published cutting edge research information OR highlighted studies where adverse effects were found.
 - So if you conducted a safety study and found no adverse effects, the journals were not interested in publishing.
 - Research information remained in the company files.

- In other words, there was no easy mechanism to make the information readily available to the public.
- Until, that is, the advent of the Internet.
 - ACC members are using this tool to address this weakness as part of their product stewardship responsibilities.

Lessons from HPV Program

- HPV Program commitment covered 17 major “endpoints,”
 - physical/chemical properties
 - environmental fate
 - ecological toxicity
 - toxicity to human health
- Standard battery of toxicity tests that is used by EPA under TSCA (and harmonized internationally under OECD).
 - Includes specific tests designed to address endpoints of concern to both adult and children’s health
- Of all the animal test studies covered by the approximately 2,200 chemicals in the HPV program, only 3% had to be generated.
- In other words, 97% of the information was available, but – until now - had not been *publicly* available.

Examples of Sources for Public Information on Chemicals

- US HPV Chemical Challenge Program:
<http://www.epa.gov/hpv/pubs/hpvrstp.htm>
- Environmental Protection Agency (EPA)'s HPV Information System:
<http://www.epa.gov/hpvis/index.html>
- Voluntary Children's Chemical Evaluation Program
<http://www.epa.gov/chemrtk/vccep/index.htm>
- Toxic Substance Control Act Test Submission database
<http://www.syrres.com/eSc/tscatsinfo.htm>
- Integrated Risk Information System (IRIS)
<http://www.epa.gov/iris/>
- European Chemical Substance Information System (ESIS)
<http://ecb.jrc.it/ESIS/>
- United Nations Environment Program (UNEP)
<http://www.chem.unep.ch/irptc/sids/OECD/SIDS/sidspub.html>
- INCHEM (developed by International Program on Chemical Safety)
<http://www.inchem.org/>

TSCA is not a static program

TSCA's flexible approach allows for

- ECAs
- HPV Program
- Voluntary Children's Chemical Evaluation Program (VCCEP)

Further evolution continues

- Nanoscale Materials Stewardship Program
- Trilateral work under North America Chemical Cooperation program

•August 20-21, 2007, Security and Prosperity Partnership meeting

Questions???

Thanks for your time!

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