



# Enhancing Implementation of the Toxic Substances Control Act

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# Enhancing Current Program

- While legislative reform is under way, EPA is using the existing Toxic Substances Control Act to the greatest extent possible.
- Comprehensive effort includes:
  - New regulatory risk management actions
  - Development of chemical-specific Action Plans which will focus risk management efforts on chemicals of concern.
  - Requiring industry to submit information needed to understand chemical risks.
  - Increasing public access to information about chemicals.



# Key Risk Management Activities

- Range of risk management activities outlined in action plans:
  - TSCA test rules and significant new use rules
  - New Toxics Release Inventory reporting
  - Design for the Environment and Green Chemistry approaches for alternatives assessment
  - TSCA Section 5(b)(4) Chemicals of Concern list
  - TSCA Section 6 actions to ban or limit uses

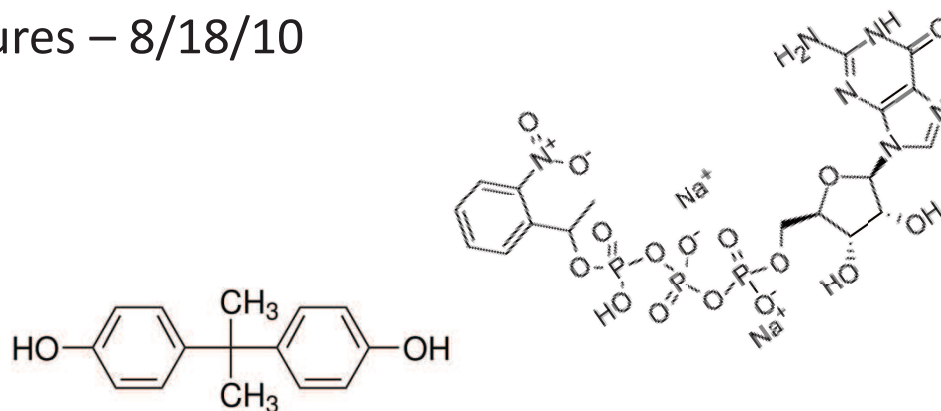
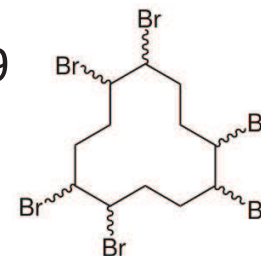


# Action Plans

- Part of Administrator Jackson's plan to enhance EPA's chemical management program:
  - Identify chemicals that pose concern to the public
  - Move quickly to evaluate and determine what actions need to be taken to address risks
  - Initiate appropriate action
- Selection Criteria:
  - Chemicals identified as persistent, bioaccumulative, and toxic
  - High production volume chemicals
  - Chemicals in consumer products
  - Chemicals potentially of concern for children's health because of reproductive or developmental effects
  - Chemicals subject to review and potential action in international forums
  - Chemicals found in human biomonitoring programs
- Actions may include initiating regulatory action to label, restrict, or ban a chemical, or to require the submission of additional data needed to determine the risk.

# Action Plans

- Eight Action Plans Released to date:
  - Eight phthalates – 12/30/09
  - Penta, octa, and decaBDE – 12/30/09
  - Hundreds of perfluorinated chemicals – 12/30/09
  - Range of short-chain chlorinated paraffins – 12/30/09
  - BPA – 3/29/10
  - 48 benzidine dyes – 8/18/10
  - Hexabromocyclododecane (HBCD) – 8/18/10
  - Range of NP/NPE mixtures – 8/18/10
- Under development:
  - Diisocyanates
  - Siloxanes



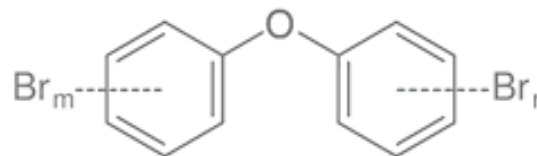
# Polybrominated Diphenyl Ethers

## Uses:

- Used as flame retardants in a number of applications, including textiles, plastics, wire insulation, and automobiles.

## Concerns:

- Concerns that certain PBDE congeners are persistent, bioaccumulative, and toxic to both humans and the environment. Various PBDEs also studied for ecotoxicity in mammals, birds, fish, and invertebrates. In some cases, current levels of exposure for wildlife may be at or near adverse effect levels.
- Not chemically bound to plastics, foam, fabrics, or other products, making them more likely to leach out.
- Manufacture and import of penta- and octaBDE phased out in 2004, but component congeners are being detected in humans and the environment, with some reports indicating levels are increasing.



# Action Plan : PBDEs

## EPA Actions:

- Initiate rulemaking to add commercial PDBE mixtures and/or the congeners to the Concern List under TSCA section 5(b)(4).
- Initiate rulemaking to propose a TSCA section 5(a)(2) significant new use rule (SNUR).
- Support and encourage the voluntary phase-out of manufacture and import of c-decaBDE.
  - Commitments received from principal manufacturers and importers to initiate reductions in the manufacture, import and sales of c-decaBDE, with all sales to cease by December 31, 2013.
  - Intend to encourage other importers of c-decaBDE to join this initiative.
  - Intend to develop DfE and Green Chemistry alternatives analysis.
- Initiate rulemaking to propose a simultaneous SNUR and the previously announced test rule for c-decaBDE.



# PBDE SNUR & Test Rule

- The SNUR and Test Rule will be proposed simultaneously
- The proposals will indicate when EPA expects manufacture and processing to cease
- If activities have ceased as expected, EPA will promulgate the SNUR designating them as significant new uses
  - No test rule would be required
- If any activities are ongoing, EPA will promulgate a test rule requiring persons who continue to manufacture, import, or process any of the PBDEs, including PBDEs contained in articles, to conduct testing



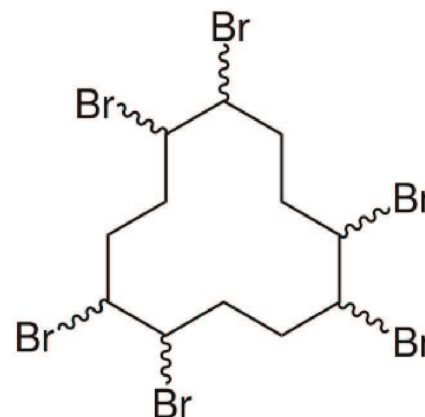
# DecaBDE Phase Out

- On December 17, 2009, as the result of negotiations with EPA, the major U.S. producers and the largest U.S. importer of decaBDE announced commitments to:
  - end production, and importation of decaBDE for all uses except military and transportation by December 31, 2012
  - end production, and importation for all uses by the end of 2013

# Hexabromocyclododecane (HBCD)

## Uses:

- Category of brominated flame retardants used in expanded polystyrene foam (EPS) in the building and construction industry, and in consumer products.



## Concerns:

- Exposure to HBCD from products and dust in the home and workplace, as well as in the environment.
- Found world-wide in the environment and wildlife. Also found in human breast milk, adipose tissue, and blood.
- Shown to bioaccumulate in living organisms and biomagnify in the food chain. Persistent in the environment and transported long distances.
- Highly toxic to aquatic organisms. Also presents human health concerns based on animal test results indicating potential reproductive, developmental and neurological effects.

# Action Plan: Hexabromocyclododecane

## EPA Actions:

- Consider initiating rulemaking under TSCA section 5(b)(4) to add to the Concern List..
- Initiate rulemaking under TSCA section 5(a)(2) to designate manufacture or processing of HBCD for use as a flame retardant in consumer textiles as a significant new use. Would also apply to imports of consumer textiles articles containing HBCD.
- Consider initiating rulemaking under TSCA section 6(a) for potentially comprehensive ban on manufacturing, processing, distribution in commerce and use, or a more targeted regulation to address specific activities.
- Initiate rulemaking to add HBCD to the Toxics Release Inventory (TRI).
- Conduct Design for the Environment (DfE) alternatives assessment of HBCD.



# Phthalates

## EPA Actions:

- Initiate rulemaking to establish a Chemical Concern List under TSCA section 5(b)(4).
- Initiate rulemaking to add the six phthalates not already on the Toxics Release Inventory (TRI).
- Prior to rulemaking under TSCA section 6(a), intend to cooperate with CPSC and FDA to more fully assess use, exposure and substitutes.
  - Plan to consider the results of the cumulative assessment currently being developed and due to be completed by CPSC in 2012 pursuant to the Consumer Product Safety Improvement Act of 2008, as well as the ongoing review of phthalates at FDA and the assessment for EPA's IRIS program.
- May pursue additional rulemaking under TSCA section 5(a)(2).
- EPA intends to conduct a Design for the Environment and Green Chemistry alternatives assessment.

# Benzidine dyes

## EPA Actions:

- Initiate rulemaking to add four dyes to the existing TSCA section 5(a)(2) significant new use rule (SNUR) for benzidine-based substances.
- Initiate rulemaking to propose a new TSCA section 5(a)(2) SNUR for benzidine congener-based dyes.
- Consider initiating action under TSCA section 6, if determined that any dyes are present in imported finished textiles, or have other ongoing uses in consumer products which present concerns.

# Perfluorinated Chemicals

## EPA actions:

- Continue with the 2010/15 PFOA Stewardship Program to work with companies to eliminate long-chain PFCs from emissions and products.
- Consider initiating rulemaking under TSCA section 6.
- EPA will develop more detailed assessments to support the TSCA section 6 rule – potentially indicating that a different approach to risk management is appropriate.
  - Other steps might include:
    - A rule addressing the PFAS sub-category expanding reach of three Significant New Use Rules (SNURs) promulgated over the past decade.
    - A rule addressing the PFAC sub-category expanding the reach of the 2010/15 PFOA Stewardship Program beyond the eight participating companies and further addressing concerns for potential PFAC exposure through use of PFAC-containing articles.
- Also continue to evaluate alternatives under EPA's New Chemicals Program and collaborate internationally to manage PFCs.

# Short-Chain Chlorinated Paraffins

## EPA Actions:

- Intend to require submission of Pre-Manufacture Notices for the SCCP, MCCP, and LCCP fractions not on the TSCA Inventory and, if appropriate, initiate action under TSCA section 5.
- Intend to initiate action under TSCA section 6(a) to ban or restrict the manufacture, import, processing or distribution in commerce, export, and use.
- Intend to further evaluate whether the manufacturing, processing, distribution in commerce, use and/or disposal of MCCPs and LCCPs should also be addressed under TSCA section 6(a).
- Intend to evaluate the potential for disproportionate impact on children and other sensitive sub-populations.



# Nonylphenol/Nonylphenol Ethoxylates

## EPA Actions:

- Support and encourage voluntary phase-out of NPEs in industrial laundry detergents
  - Expand the scope of Safe Detergent Stewardship Initiative, and encourage those industries to make commitments under SDSI.
- Develop an alternatives analysis and encourage elimination of NPE in other industries that discharge NPEs to water (i.e. the pulp and paper processing and textile processing sectors)
- Initiate rulemaking to simultaneously propose a significant new use rule (SNUR) under TSCA section 5(a) and a test rule for NP and NPEs under TSCA section 4
- Issued an advance notice of proposed rulemaking (ANPRM) for NP and NPEs on June 17, 2009.
- Consider rulemaking under TSCA section 5(b)(4) to add to the Concern List
- Initiate rulemaking to add to the Toxics Release Inventory (TRI)

# Bisphenol A

## EPA Actions:

- Initiate rulemaking under TSCA section 5(b)(4) to add to the Concern List.
- Consider initiating rulemaking under TSCA section 4(a) to develop data on environmental effects relevant to a further determination that BPA either does or does not present an unreasonable risk of injury to the environment.
- Initiate alternatives assessment activities under DfE program to encourage reductions in BPA releases and exposures.
  - One activity, initiated in April 2010, will address thermal paper coatings used in applications such as cash register receipts.
  - Additionally, intend to initiate alternatives analyses for BPA used in foundry castings since
- Will continue to consult and coordinate closely with FDA, CDC, and the National Institute of Environmental Health Sciences to better determine and evaluate the potential health consequences.

# Inventory Update Rule

- Proposed in August to amend the reporting requirements of the TSCA Inventory Update Reporting (IUR) rule.
- Purpose is to meet four primary goals: (1) Tailor the information collected to better meet the Agency's overall information needs; (2) Increase its ability to effectively provide public access to the information; (3) Obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory; and (4) Improve the usefulness of the information reported.
- Rule is targeted for finalization in 2011

# Some Proposed Changes in Inventory Update Rule

- Require reporting if the production volume of a chemical substance met or exceeded the 25,000 lb. threshold in any calendar year since the last principal reporting year (proposed method would be effective after the 2011 submission period).
- Require reporting of production volume for all years since the previous principal reporting year (i.e., 2005).
- Eliminate the 300,000 lb. threshold for processing and use information, thereby requiring all reporters of non-excluded substances to report information in all parts of the IUR Form U.
- Revise the list of consumer and commercial product categories for the reporting of consumer and commercial use information.
- Require upfront substantiation when processing and use information is claimed as confidential business information (CBI).
- Change the reporting frequency from every five years to every four years.
- Eliminate the 25,000 lb. threshold for certain chemical substances that are the subject of particular TSCA rules and/or orders and to require manufacturers (including importers) of such chemicals to report under the IUR rule, regardless of the production volume.

# Additional Risk Management Activities

## Nanoscale Materials

- Chemical substances as defined by TSCA
- More than 100 new chemical notices for NMs have been received since 2005
- The Agency has taken a number of actions to control and limit exposures to these NMs including:
  - limiting the uses of the nanoscale materials,
  - requiring the use of personal protective equipment, such as impervious gloves and NIOSH approved respirators,
  - limiting environmental releases, and
  - requiring testing to generate health and environmental effects data.

# Additional Risk Management Activities

## Nanoscale Materials

- OPPT conducted a voluntary reporting program for nanoscale materials based on existing chemicals
- As a follow-up to the voluntary program EPA is developing the following proposed actions under TSCA.
  - SNUR to require reporting of new nanoscale materials that are existing chemicals
  - Section 4 rule to require testing of certain nanoscale materials
  - Section 8(a) rule to require reporting of available use, production volume, exposure, and toxicity data for existing nanoscale materials

# Increasing Transparency

- **Current Efforts:**

- Addition of 530 chemicals on public version of TSCA Inventory
- New policy for review of Confidential Business Information (CBI) chemical identity claims for notices of substantial risks
- Free access to consolidated Inventory – EPA and Data.Gov websites
- Integrated TSCA facility and chemical information into Envirofacts
- New policy for review of CBI chemical identity claims for all health and safety studies
- Assistant Administrator letter to industry trade associations and 32 companies urging release of unwarranted CBI claims
- Proposed IUR modifications for 2012 reporting





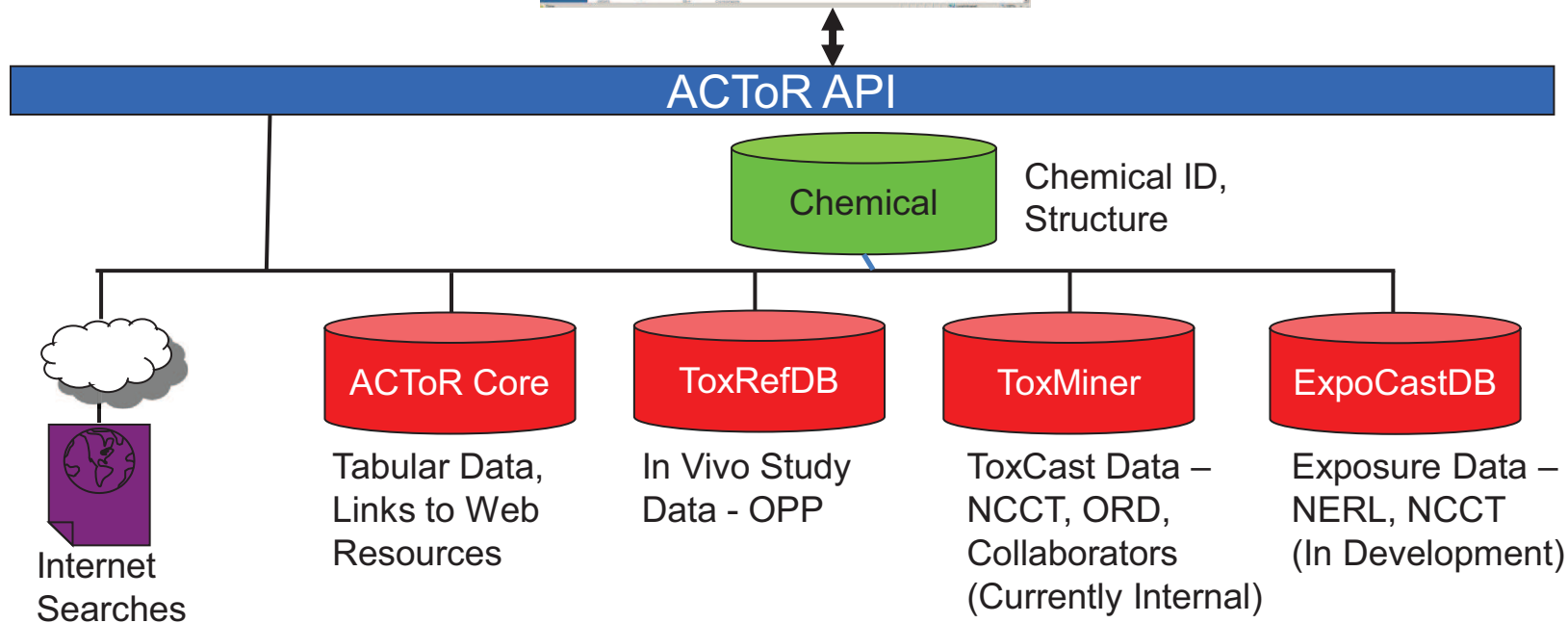
# ToxRefDB (Toxicity Reference Database)

- Captures over 30 years and \$2 billion of in vivo animal testing data in a publically accessible & searchable format.
- Stores detailed study design, dosing, and observed treatment-related effects using standardized vocabulary.
- Three study types
  - Chronic/Cancer rat and mouse
  - Rat multigenerational reproduction
  - Rat & Rabbit developmental
- ToxRefDB currently includes detailed study and effect information on 474 chemicals, primarily pesticide active ingredients, and will continue to expand.
- Enables linkages to other public hazard, exposure and risk resources by integrating with ACToR (Aggregated Computational Toxicology Resource).

# ACToR--Aggregated Computational Toxicology Resource



<http://actor.epa.gov/>



# Resources

- To learn more about TSCA and EPA's Enhanced Chemical Management Program:

<http://www.epa.gov/opptintr/>

- For more information in ToxRefDB:

<http://www.epa.gov/ncct/toxrefdb/>

<http://www.epa.gov/ncct/actor/>