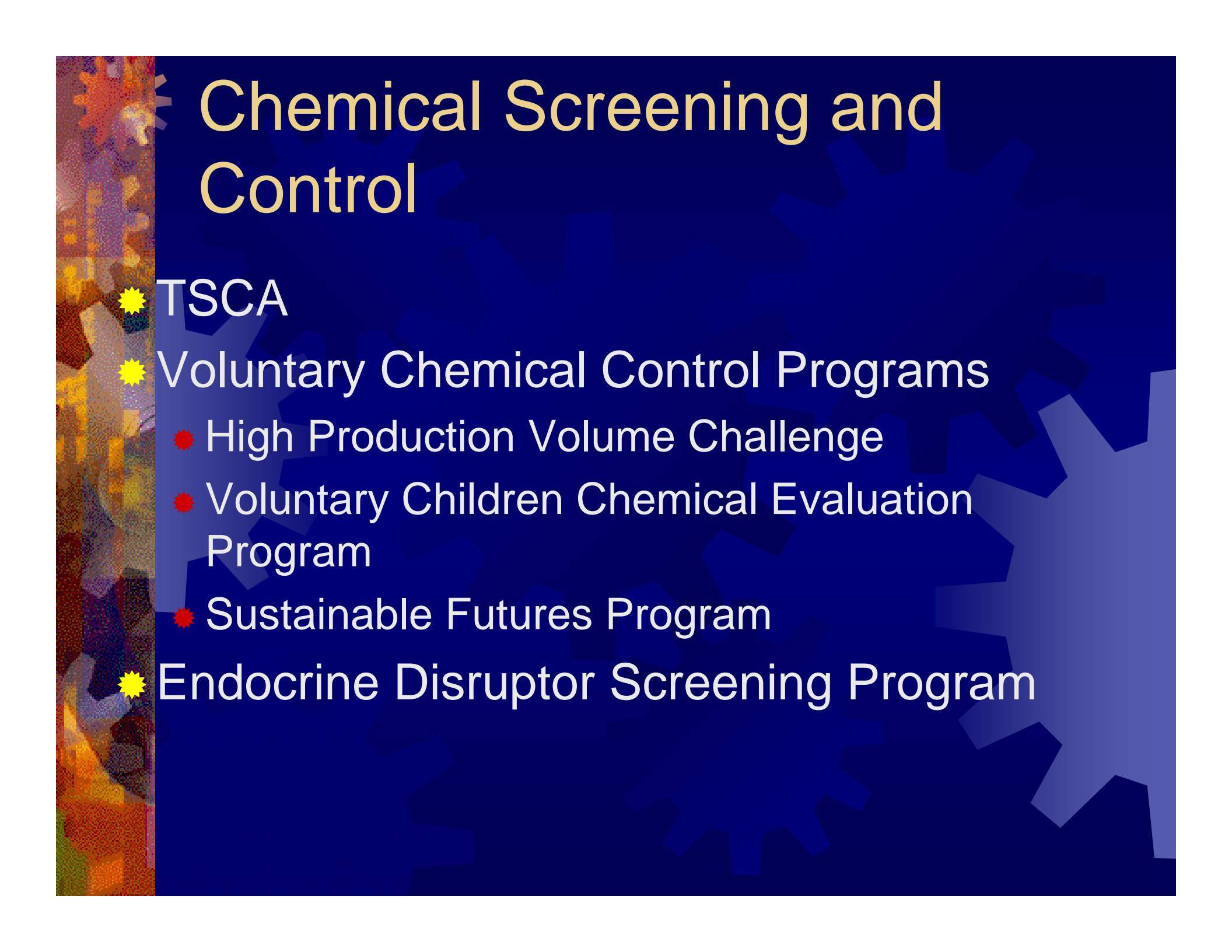


The background is a dark blue gradient with several overlapping gears of various sizes and shades of blue. On the left side, there is a vertical strip with a colorful, abstract, and somewhat pixelated pattern in shades of orange, yellow, and brown.

U.S EPA Chemical Assessment and Control Programs

GLBTS Summer Meeting
September 15, 2005
Chicago, IL



Chemical Screening and Control

★ TSCA

★ Voluntary Chemical Control Programs

● High Production Volume Challenge


● Voluntary Children Chemical Evaluation Program

● Sustainable Futures Program

★ Endocrine Disruptor Screening Program

TSCA

- ★ Promulgated in 1976
- ★ TSCA allows EPA to control the entire lifecycle of a chemical
- ★ Of 82,000 currently registered chemicals, 62,000 were on the market
 - ★ (Over 700 new chemicals introduced into the market each year)
- ★ TSCA does not cover nuclear material, firearms and ammunition, pesticides, food, food additives, tobacco, drugs and cosmetics



New Chemicals: Pre-Manufacturing Notice

- ☀ 90 day notice prior to market
- ☀ Industry must supply EPA with information on:
 - ☀ Volumes
 - ☀ Intended uses
 - ☀ Potential exposure and release levels
 - ☀ Disposal and by-products
 - ☀ Test data in possession of company

PMN

- ★ EPA predicts exposure and toxicity using screening models (QSAR)
- ★ About 80% of new chemicals submitted are screened out as requiring no further evaluation, if
 - ★ EPA determines that chemical has potential for low toxicity to HH and E, or
 - ★ Use, exposure and release pose limited risks to HH and E



On basis of PMN review, EPA can

- ★ Take no action
- ★ Require controls in use, manufacturing, processing, distribution in commerce, or disposal of a chemical pending development of test data
- ★ Ban or otherwise regulate chemical pending the receipt and evaluation of test studies performed by the chemical manufacturer
- ★ EPA reviews have resulted in some action being taken on over 3500 of the 32,000 new chemicals submitted for review

Significant New Use Rule

- ★ EPA determines that use of a chemical constitutes a significant new use, in which case a significant new use notice would be required.
- ★ When EPA controls a new chemical through a Consent Order with particular manufacturer, follow with a SNUR that applies to all manufacturers.
- ★ EPA has used this for about 579 of the 32,000 chemicals submitted for review.



Testing Existing Chemicals

- ★ No systematic review of existing chemicals required by TSCA, however,

- ★ TSCA authorizes EPA to require testing if it makes a finding that the chemical 1) may present an unreasonable risk of injury to health or the environment, or 2) is or will be produced in significant quantities and a) there may be significant or substantial human exposure to the chemical, or b) it enters or may reasonably anticipated to enter the environment in significant quantities



Testing Existing Chemicals

- ★ Of the 62,000 on the market prior to TSCA, EPA has used this authority for fewer than 200 substances

- ★ *HPV attempts to address shortcomings in available data*



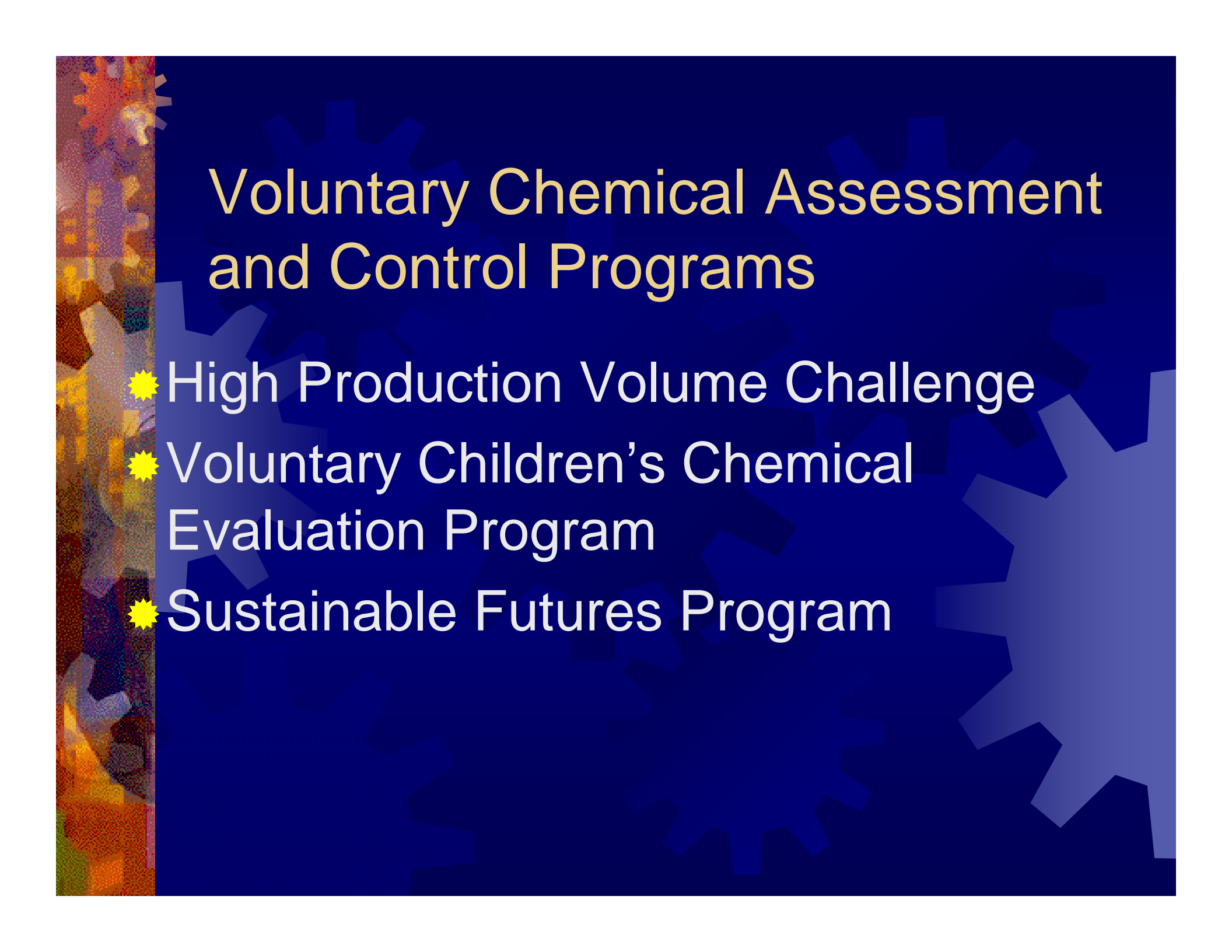
Chemical Regulation

★ If EPA finds that a chemical presents or will present an unreasonable risk, EPA can promulgate a rule that bans or restricts production, processing, disposal or use, or requires warning labels be placed in the chemical. EPA must choose the least burdensome requirement that will adequately protect against risk.



Chemical Regulation

- ★ Since 1976, EPA has banned or limited production or restricted use of five chemical, or chemical classes: PCBs, chloroflouroalkanes, dioxin, asbestos, and hex chrome).
- ★ EPA has issued SNURs for 160 existing chemicals as well.



Voluntary Chemical Assessment and Control Programs

- ★ High Production Volume Challenge
- ★ Voluntary Children's Chemical Evaluation Program
- ★ Sustainable Futures Program



High Production Volume Challenge Program

- ★ Started in 1998
- ★ 2200+ chemicals manufactured or imported over 1 million pounds/year
- ★ Represent approximately 95% of US domestic production and use by volume
- ★ Industry voluntarily sponsors each HPV chemical – 300 companies to date



High Production Volume Challenge Program

- ★ Industry provides EPA with 17 types of information, including physical-chemical properties, fate, ecological and human toxicity
- ★ Identical to Organization for Economic Cooperation and Development (OECD) Screening Information and Data Sets Program (SIDS)
- ★ Currently 300 “orphan” chemicals
- ★ No “TSMP”



Voluntary Children's Chemical Evaluation Pilot Program

- ★ Prompted by 1998 Chemical Right to Know Initiative, which included a provision to “obtain data for evaluating the potential health effects of industrial chemicals on children”
- ★ Started in 2000
- ★ 23 chemicals initially selected – based on presence in human tissues, as well as presence in food, water and air
- ★ Mainly VOCs, but includes PDBEs



Voluntary Children's Chemical Evaluation Pilot Program

- ✦ Industry sponsorship (20 or 23 so far)
- ✦ 3 tiers of assessment
- ✦ EPA will collect all 20 tier 1 data in 4-5 years
- ✦ Make hazard/exposure/risk assessment data publicly available
- ✦ No "TSMP"



Tier 1

Acute toxicity

Repeated dose toxicity with reproductive and developmental toxicity screens

Bacterial reverse mutation assay

In vitro or *in vivo* chromosomal aberrations or *in vivo* micronucleus test

Tier 2

Subchronic toxicity

Prenatal developmental toxicity

Reproductive and fertility effects

In vivo chromosomal aberrations or *in vivo* micronucleus test

Metabolism and pharmacokinetics

Tier 3

Neurotoxicity screening battery
Carcinogenicity

Developmental neurotoxicity



Sustainable Futures Program

- ★ Started 2000

- ★ Voluntary program to help industry design environmentally sustainable chemicals

- ★ EPA provides

- Training on EPA risk screening models
- Expedited review
- SBA
- Tech assistance
- Public recognition



Endocrine Disruptor Screening Program

- ★ Mandated by 1996 Food Quality Protection Act, which amends the Federal Food, Drug and Cosmetic Act, and the 1996 amendments to the SWDA
- ★ Intended to screen pesticides, chemicals and other environmental contaminants for potential effect of estrogen, androgen and thyroid hormone systems



Three Major Parts to EDSP

★ Methods

- ★ FACA is developing test method assays – finalize by 2007, and commence testing

★ Selection

- ★ Initial round of 50-100 chemicals, to be determined
- ★ Federal Register Notice due in 2005 on methodology for selecting chemicals

★ Regulatory Procedures to Require Screening