



Overview of the New Chemicals Premanufacture Process

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Toxic Substances Control Act (TSCA) - An Overview

- Provides basic authority for chemicals in US
- TSCA provides broad authority to:
 - Gather information on new and existing chemical substances and mixtures
 - Require testing of certain chemicals
 - Screen and control new and existing chemicals
 - Control existing chemicals that present risk
 - Coordinate with other Federal and State agencies



TSCA - An Overview

- an “existing” chemical substance is on the TSCA Inventory as being manufactured or imported in the U.S.
- a “new” chemical substance is one that does not appear on the TSCA Inventory



Section 5 of TSCA

TSCA Section 5 requires a manufacturer or importer of a new chemical substance to submit a “premanufacture notice” (PMN) to EPA 90 days before the date of intended start of production or import of the subject chemical



Role of New Chemicals Program

- **Gatekeeper Responsibilities**
 - Designed to prevent health and/or environmental risks before they occur
- **Advocate for Environmental Stewardship**
 - Designed to encourage the development by Industry of safer and greener new chemicals



Gatekeeper Responsibilities

Process Overview

- Evaluation of risks from new chemicals are considered throughout their product life cycle
- Focus is on determining “unreasonable risk” - if found, EPA identifies needed risk management or other actions.
- Such new chemicals can enter commerce but the company must meet any regulatory requirements.
- If EPA does not take an action, without additional restrictions the new chemical may enter US commerce



Program Overview

- Designed to prevent health and/or environmental risks before they occur
- Regulatory decisions are often made in the absence of test data on the specific chemical
- Proven track record: over 47,000 Section 5 notices reviewed to date



Notifications

- PREMANUFACTURE NOTIFICATION (PMN)
 - New industrial chemicals not otherwise excluded are subject to new chemical notification requirements
- INTERGENERIC MICROORGANISM NOTIFICATION
 - Intergeneric microorganisms are subject to new chemical notification requirements



Is Your Substance Subject to a PMN?

- Intent to Manufacture (Import) for Commercial Purpose
- Not Excluded by Statute or Regulation
- Not on the TSCA Inventory
- Defined as Chemical or Microorganism



Exclusions – By Statute

- FOOD, FOOD ADDITIVES, DRUGS, COSMETICS OR DEVICES
- PESTICIDES
- TOBACCO AND TOBACCO PRODUCTS
- FIREARMS, NUCLEAR SOURCE MATERIALS



Exclusions – By Regulation

- MIXTURES
- BYPRODUCTS / IMPURITIES
- NON-ISOLATED INTERMEDIATES
- SUBSTANCES IMPORTED AS COMPONENTS OF AN ARTICLE



Who Submits A PMN?

- U.S. Manufacturer
- U.S. Principal Importer
- Manufacturer, Processor, or User of Excess R&D substance for Non-Exempt Commercial Purpose



Types of TSCA Section 5 Submissions

- Premanufacture Notification (PMN)
- Consolidations
- Joint Submission
- Letter of Support
- Exemption Applications



PMN Exemptions

- LOW VOLUME EXEMPTION (Regulatory)
 - 10,000 kilograms or less per year
- LOW EXPOSURE/LOW RELEASE EXEMPTION (Regulatory)
 - Must meet specified exposure/release conditions
 - No production volume limitation



PMN Exemptions - continued

- POLYMER EXEMPTION (Regulatory)
 - Must meet polymer definition and eligibility criteria
 - EPA notification not required
- TEST MARKET EXEMPTION (Statutory)
- RESEARCH & DEVELOPMENT EXEMPTION (Statutory)
 - Small quantities solely for the purposes of scientific experimentation, research, or analysis
 - No limits on production volume
 - No reporting required, only recordkeeping



Polymer Exemption

- Ineligible Polymers
 - Degrade, decompose, or depolymerize
 - Chemical identity (monomers and other reactants greater than 2%) included in a “new” chemical substance
 - Water-absorbing polymers with number-average molecular weight equal to or greater than 10,000 daltons

Process

	Application	Time for Review	User Fee Costs	Results	Workload (EPA Resources)
Test Market	EPA Form preferred	45 days	None	Grant or Deny	New Chemicals Review Team
Low Releases/ Low Exposure	EPA Form	30 days	None	Grant or Deny	New Chemicals Review Team
Research & Development	Record-Keeping (Industry)	Not Applicable	None	Not Applicable	None
Polymer	Postcard Notification	Must be submitted by 01/31 of the year subsequent to initial manufacture	None	Submitter must meet definition	Notification Management of Postcards
Low Volume	EPA Form	30 days	None	Grant or Deny	New Chemicals Review Team



Required Information for Notification

- Chemical Identity/Structure
- Description of Uses
- Production/Importation Volume
- Description of Byproducts
- Description of Human Exposure
- Description of Disposal Practices
- Available Health/Environmental Effects Test Data

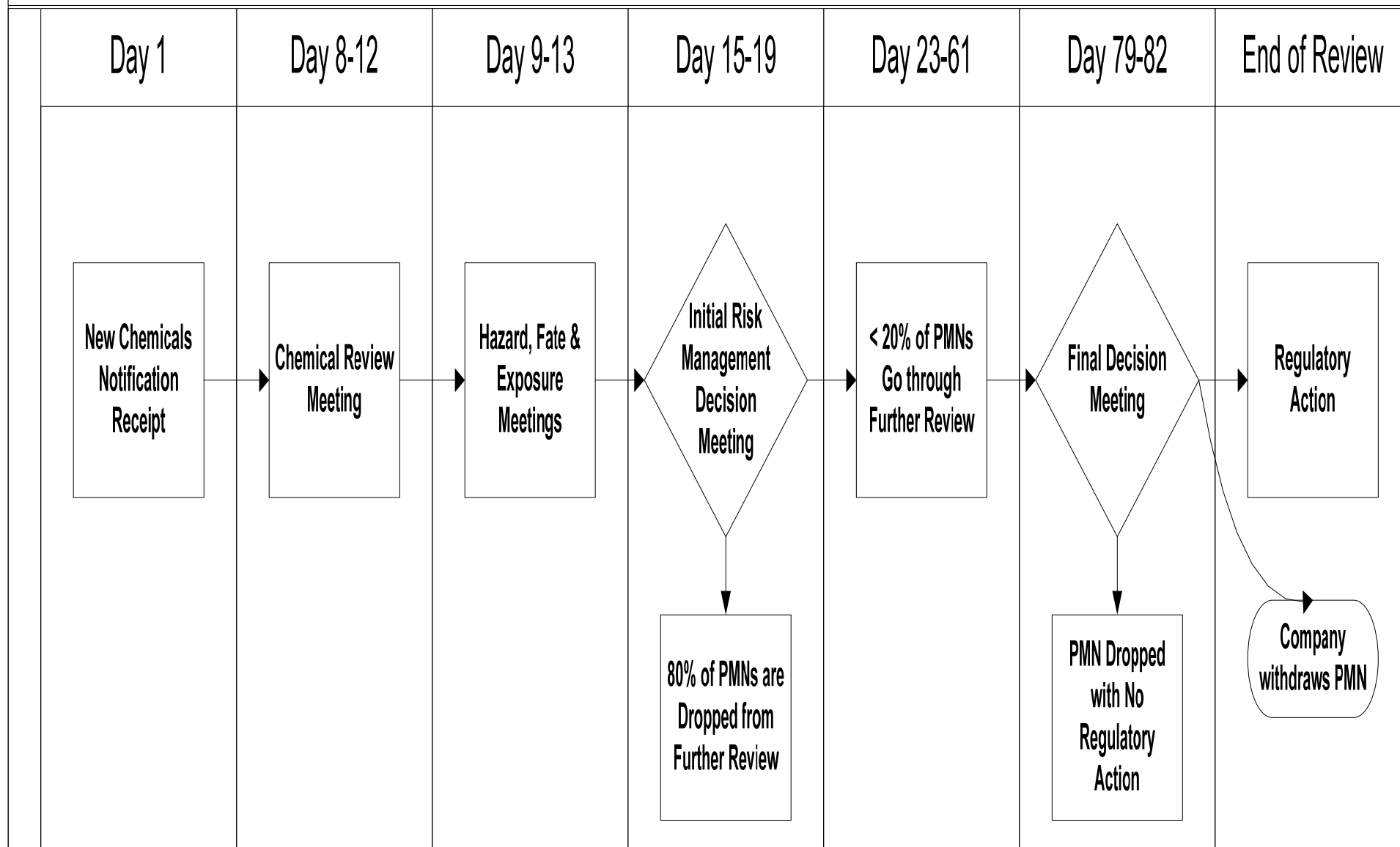


Incoming Data Overview

No test data requirements

- Regulatory decisions are often made in the absence of data
 - 50% of PMNs contain no test data
- The majority of the submitted toxicity test data pertains to human health
- Minimal environmental effects/fate data submitted

New Chemicals Review Process





Risk Assessment/Risk Management at Initial Decision Meeting Focus Meeting

- Risk management decision meeting by a multi-disciplinary group
- Reporting of hazard and exposure assessments (initial screen)
- Handle “low concern” chemicals and chemical categories
- Determination of significant risk for categories, substantial production, significant and/or substantial exposure
- Make decisions on categories and exposure based actions or to initiate Standard Review

Outcomes:

- Drop from further review (80%)
- More Detailed Assessment (20%)



Risk Assessment/Risk Management at Final Decision Meeting

- Consider results of the detailed assessment
- Factor in hazard, exposure, risk, risk/benefit, alternatives, and regulatory history for related PMN cases, etc.
- Outcome
 - Final decisions are made on the 20% of PMN cases continued into this review, of these about $\frac{1}{2}$ are dropped, $\frac{1}{4}$ are withdrawn by submitter in face of regulatory action, and control measures are taken on remaining $\frac{1}{4}$.



Final Risk Management Decisions

- Drop
- Regulate:
 - 5(e) Consent Order (a legal agreement between EPA and the company) which can include:
 - Control exposures/uses
 - Require testing
 - Take other action
 - 5(e) Significant New Use Rule (extends the risk management decisions to any other company interested in the use of the chemical)
 - Non 5(e) Significant New Use Rule (used to control uses other than the ones stated in the submission that could result in increased exposures to, or release, of the PMN substance)
 - Suspension, Ban Pending Upfront Testing



Notice of Commencement

- Submit within 30 days of first manufacture
- Must be submitted by PMN submitter
- Substantiate CBI Claims



Approaches to Environmental Stewardship

- Pollution Prevention Recognition
 - Promotes source reduction, greener chemistry, and greener engineering practices through recognition
- Sustainable Futures
 - EPA program to make its SAR tools available to Industry for use in research and development in order to design safer and greener new chemicals



Attachments

Supplemental Information



Definition of a Polymer

- *A polymer is a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weight wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.*



Approaches for Nanoscale Materials under TSCA

- Many nanoscale materials (NMs) are chemical substances as defined by the Toxic Substances Control Act (TSCA)
- NMs not on the TSCA Inventory are new chemicals and a Pre-Manufacture Notice (PMN) is required before commencement of manufacture
- There is presently no similar requirement for NMs that are existing chemicals, i.e. already on the TSCA inventory
- The limited information currently available indicates that NMs may have different toxicity and/or exposure characteristics than their “macro” counterparts



TSCA New Chemicals Program Experience/Issues

- PMN submissions on nanosized chemicals are being received and reviewed but most have not met other elements of National Nanotech Initiative (NNI) definition -- unique properties or deliberately engineered -- other than:
 - A low release, low exposure exemption has been granted (carbon nanotube)
- There have been several recent company meetings on pending new chemical NMs
- General approach has been to permit limited manufacture of nanosized new chemicals under appropriate controls via use of consent orders and Significant New Use Rules (SNURs)



Chemical Categories

- Currently 55 categories - human health and ecotoxicity
- Based on test data
- Identifies endpoints of concern
- Provides testing recommendations
- Delegated authority on structural analogues of these category compounds
- EPA needs relevant data to refine concerns



TSCA, Section 5(e) Regulatory Decisions

The information . . . is insufficient . . . to permit a reasoned evaluation . . . such activities . . .

- May present an unreasonable risk of injury to health or the environment, or . . .
- Will be produced in substantial quantities, and . . . enter the environment in substantial quantities or there . . . may be significant or substantial human exposure . . .



General Guidance on Risk Judgments

- Human health
 - Estimated risk for cancer $> 1.0E-6$
 - Non-cancer endpoints, Margin Of Exposure (MOE) < 100
- Aquatic species
 - Acute risk, surface water concentration exceeds the Concentration of Concern ≥ 4 days/yr
 - Chronic risk, surface water concentration exceeds the Concentration of Concern ≥ 20 days/yr



Policy on Persistent, Bioaccumulative, and Toxic (PBT) New Chemicals

- Serves to alert industry to this issue
- PBT Policy Statement published at 64 FR 60194
- We will take action when:
 - Persistence (transformation half-life) is > 2 months
 - Bioaccumulation (Fish BCF or BAF) is $\geq 1,000$
- Identification of Potential Hazard to Human Health and/or the Environment

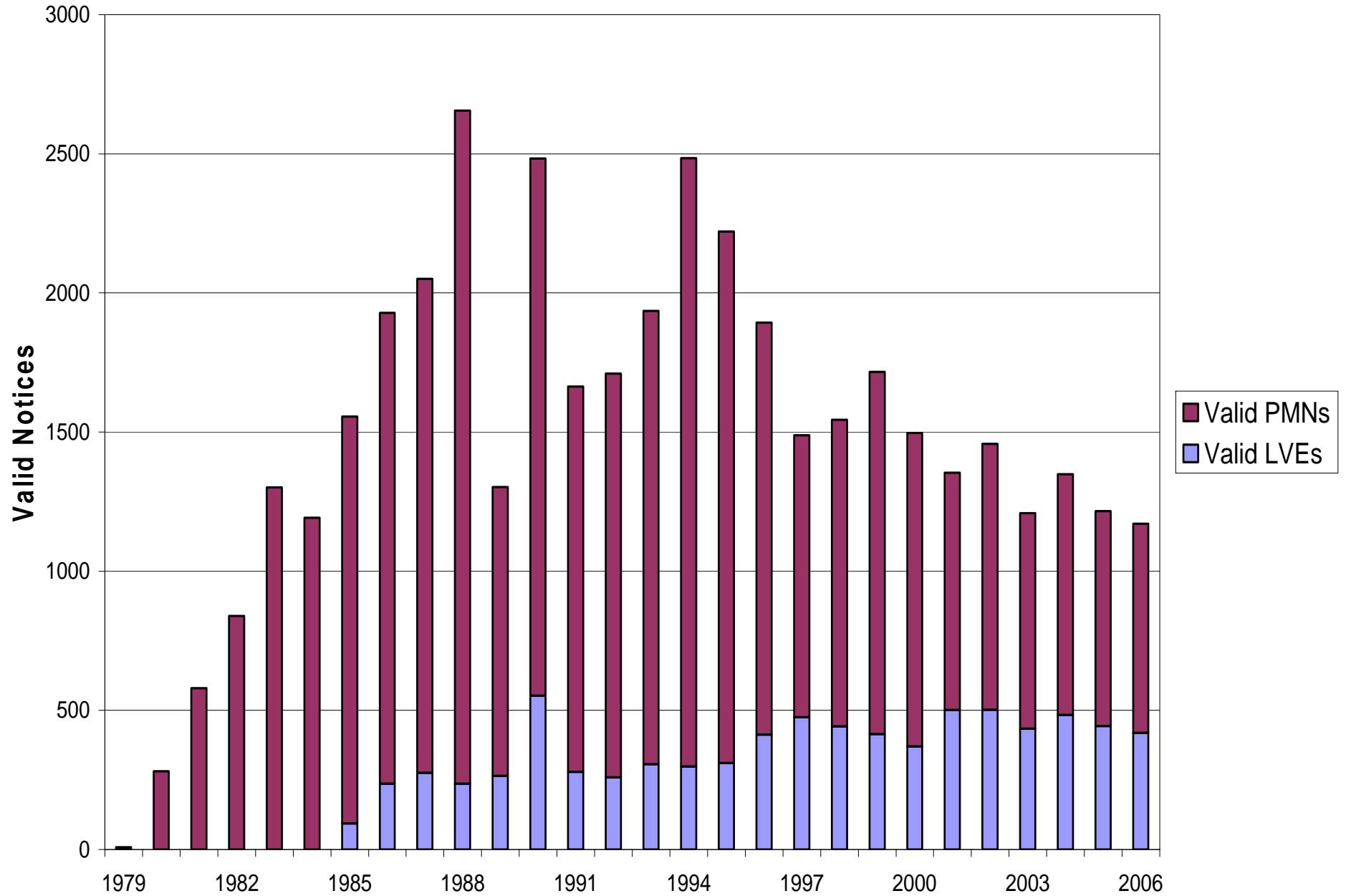


Potential Control Measures in 5(e) Orders

MAY INCLUDE:

- Testing
- Protective Equipment Requirements
- Worker Training Programs
- Distribution/Use/Disposal Restrictions
- Labels, MSDS, and Notification Letters
- Restrictions on Releases to Water/Air
- Recordkeeping Requirements
- Production/Importation Volume Testing Trigger
- New Chemical Exposure Limit (NCEL)
- Product Stewardship Programs

Total PMN and LVE submissions





Additional Information

- New Chemicals Program
www.epa.gov/oppt/newchems
- Chemistry Assistance Manual
www.epa.gov/oppt/newchems/chem-pmn/index.htm
- Exposure Assessment Models
www.epa.gov/oppt/exposure
- Hazard and Risk Assessment Screening Tools (used in Sustainable Futures Program)
www.epa.gov/oppt/p2framework



THANK YOU