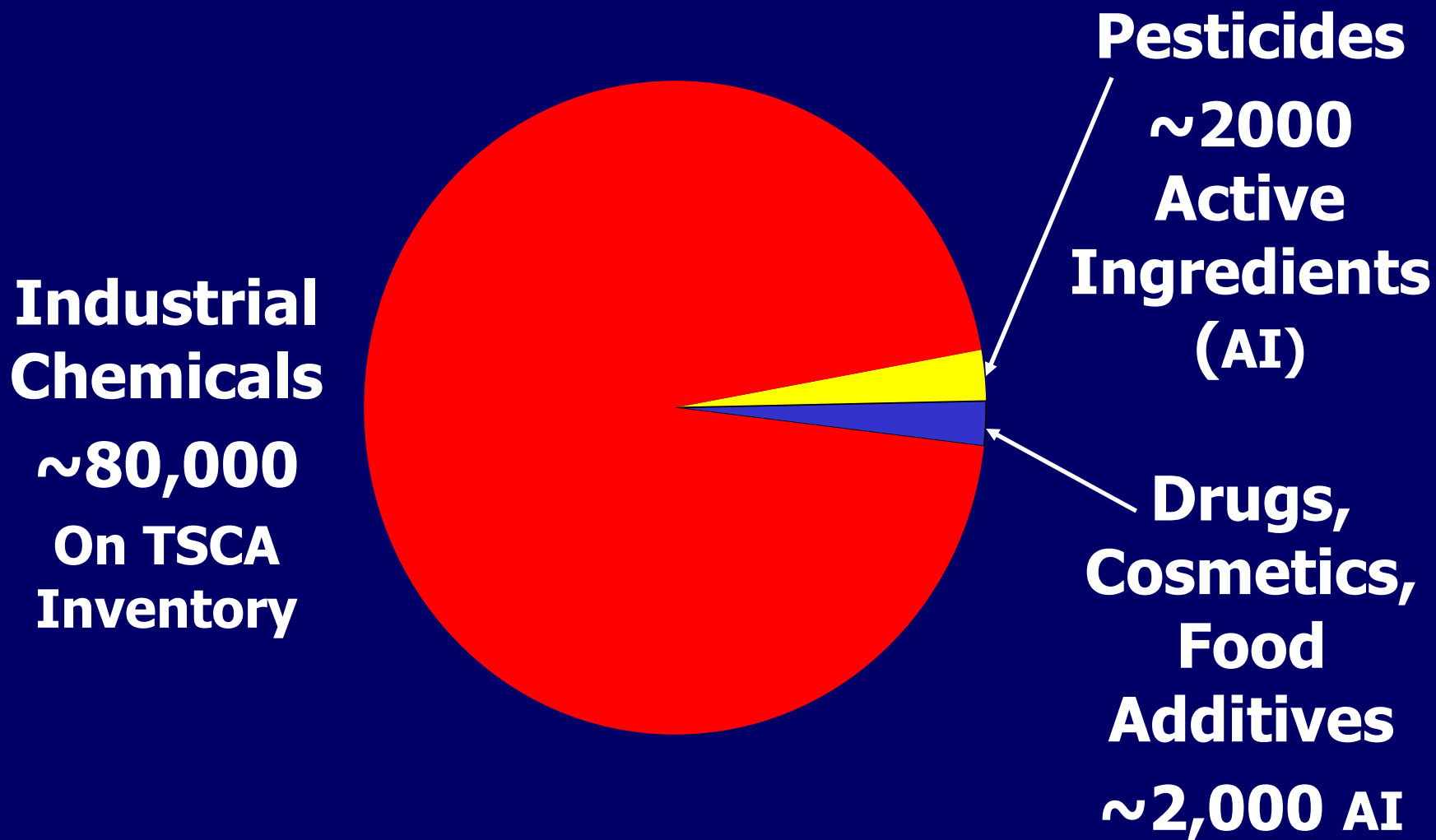


P2 Framework Models Overview

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Chemicals in Commerce



Challenge: Evaluating Chemicals In The Absence Of Data Under TSCA

- ☐ Congress gives EPA authority to evaluate / regulate new chemicals
- ☐ EPA must complete its review in 90 days.
- ☐ Proponents of manufacture of New Chemicals are not required to do any testing.
- ☐ EPA can require testing
- ☐ EPA reviews about 2,000 PMNs per year

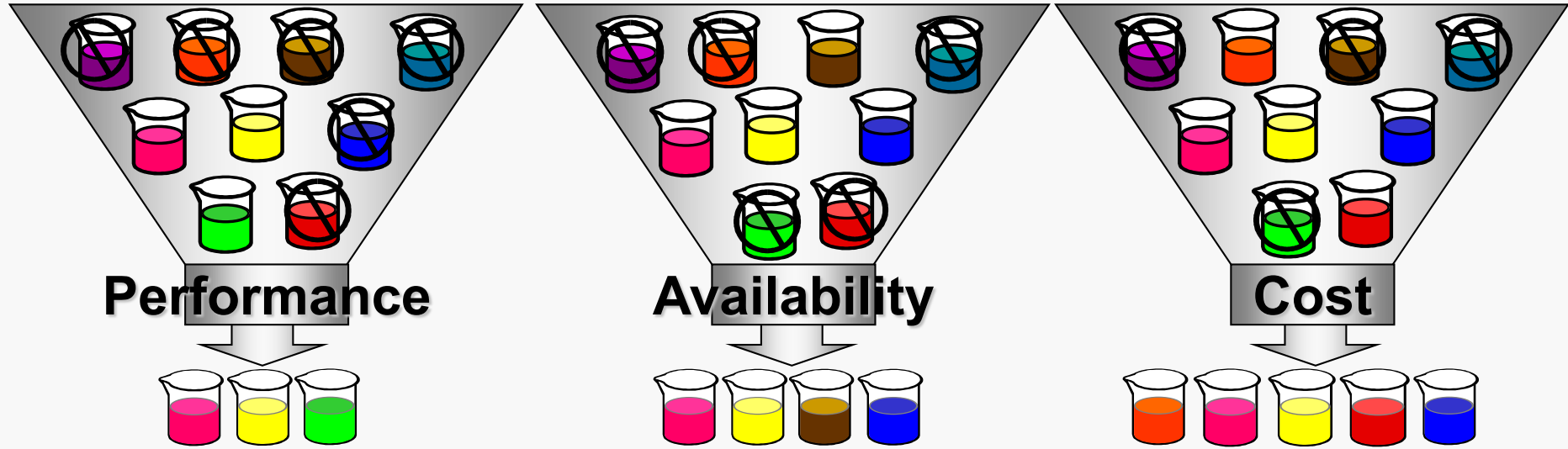
EPA's Approach to the Evaluation Of New Chemicals In the Absence of Data

- ☐ Nearest analogue analysis (Are there data on a closely related structure?)
- ☐ Structure Activity Relationships (SAR)
- ☐ Cancer Expert System
- ☐ Computational approaches for estimating toxicity, fate, exposure from structure
 - Physical / chemical properties
 - Environmental fate
 - Aquatic toxicity
 - Exposure (general population, consumer, occupational, and aquatic, etc.)

EPA's P2 Framework

EPA has automated many of the SARs, computational methods, expert systems, etc., used to predict hazard, exposure and associated risk, based on an analysis of structure and combined them into the P2 Framework.

R&D Process - Status Quo



Chemicals Meeting All the Desired Criteria Will Be Evaluated Based on Additional Criteria:

Often no toxicity screening until this point



Final Product Development



EPA Is Making the P2 Framework Available to Industry

Models helped industry:

- ☰ Pre-screen chemical alternatives**
- ☰ Understand potential risks of product alternatives under consideration at R&D**
- ☰ Understand potential risk trade-offs of alternatives under consideration**
- ☰ Reduce product development costs**
- ☰ Stimulate development of environmentally preferable products and processes**

P2 Framework Models

☰ Screening models: NOT replacing measured data!

☰ P2 Models predict information in 4 areas:

- Physical / chemical properties
- Environmental fate properties
- Hazard to humans and aquatic environment
- Exposure / risk

Risk-related Information From P2 Framework Models

- ☐ Once released, will the chemical go to air, water, soil, sediment? [EPI Suite™]
- ☐ How long will the chemical stay in media? [EPI Suite™]
- ☐ Will the chemical present a hazard? [Oncologic & Ecosar]
- ☐ Could this be a PBT? [PBT Profiler]
- ☐ Who will be exposed and for how long? [ChemSTEER, E-FAST]

P2 Framework Models

Phys/Chem Properties

EPI Suite™

MP, BP, VP

KOW

WS

KOC

Henry's law
constant

Environmental Fate

EPI Suite™

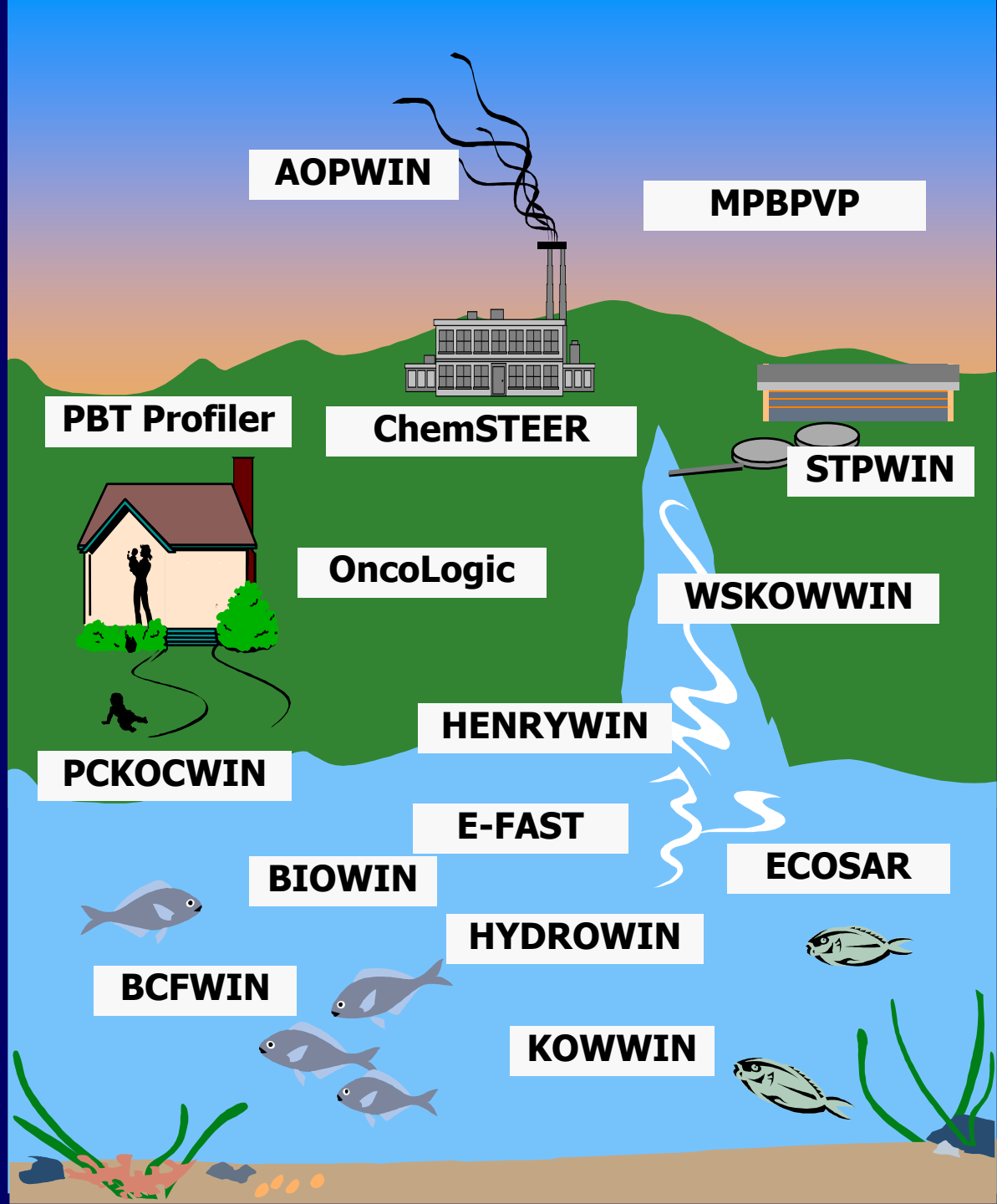
AOP

Fish BCF

Biodegradation

Hydrolysis

Removal in WWTP



P2 Framework Models

Hazard

☰ ECOSAR

Aquatic Toxicity

☰ OncoLogic

Carcinogenicity

☰ PBT Profiler

PBT potential

Exposure / Risk

☰ ChemSTEER

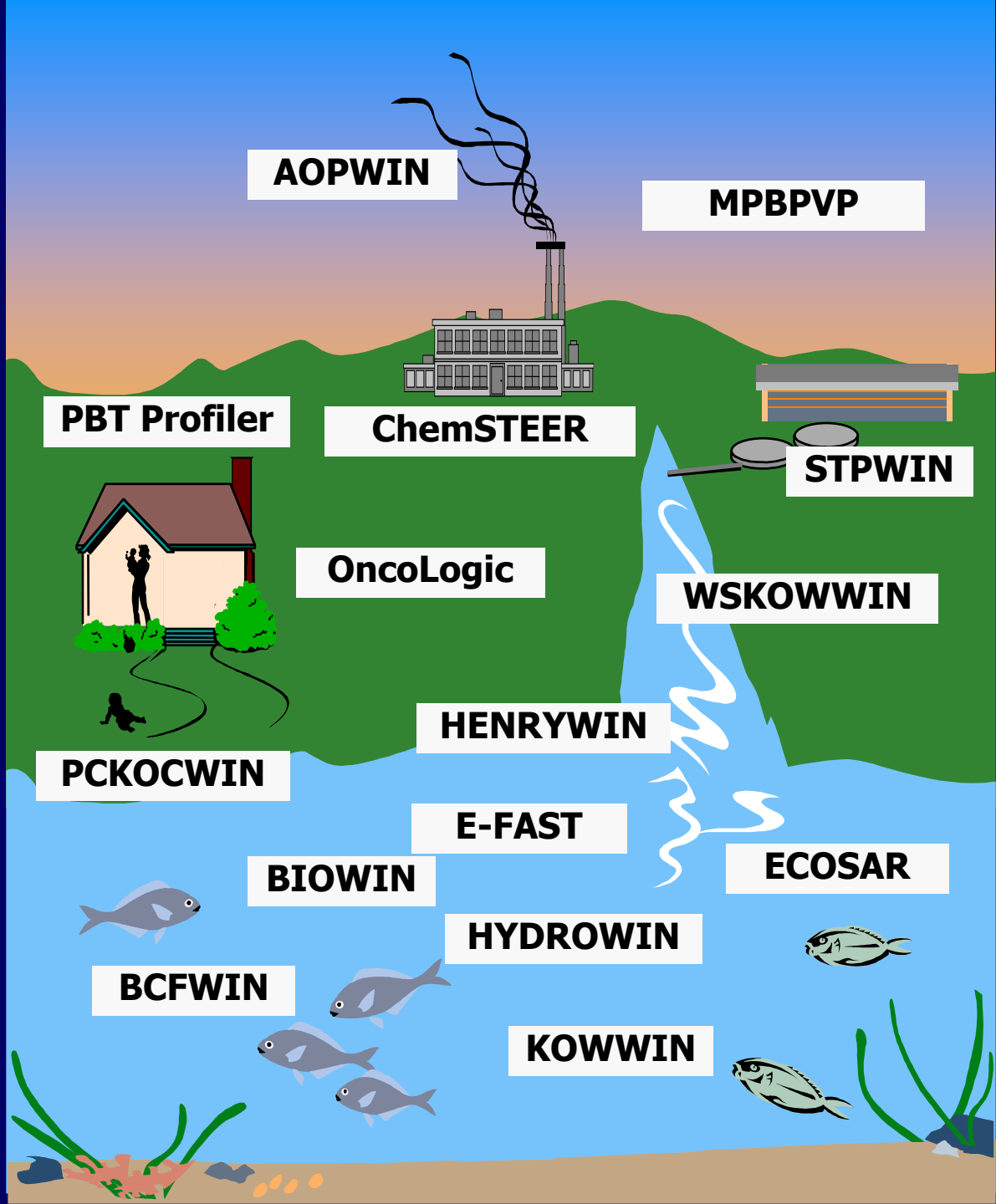
Release amounts

Worker exposure

☰ E-FAST

Consumer dermal & inhalation exposure

Human PDRs



P2 Framework Workshops

- Numerous hands-on training workshops have been held nationwide
- Participants from several hundred companies

P2 Framework Partnerships

- Partnerships formed with dozens of companies
- Companies using P2 Models in product development

But Do These Methods Work?

Some Comments from Industry

- ☰ “...a great help in flagging potential risk issues.”
(Hercules)
- ☰ “The P2 Framework helps us understand potential risk-related concerns associated with chemical substances under development” (Shell)
- ☰ “By using the P2 Framework, we can...develop and manufacture safer and more sustainable products”
(PPG Industries)
- ☰ “...particularly useful when used to minimize the potential synthesis or generation of hazardous wastes...” (Eastman Kodak)
- ☰ “EPA...may underestimate the true value of these tools” (Procter & Gamble)

Project XL => Reg. Relief => Sustainable Futures

- Eastman Kodak & PPG Industries
Project XL Experiments
- Kodak and PPG incorporate P2
Framework and PBT Profiler at R&D
- Kodak and PPG develop inherently
safer chemicals - no regulation
- PPG: predictive capability
Kodak: business benefits
- Kodak and PPG eligible for reg. relief

Kodak: The Business Benefits of Risk Screening

- ☐ Reduced product development costs by 13% to 100% for each PMN
- ☐ Decreased time to market
- ☐ Decreased generation of chemical waste
- ☐ Increased HS&E contribution
- ☐ Tellus Report: Kodak's experience (Published in BNA August 29, 2001)
 - Case study saved Kodak \$750K - \$1,000K
 - Decreased time to market by 1 1/2 - 2 years

But Do These Methods Work?

Validation Studies by PPG Scientists

☰ Comparison of Aquatic Toxicity Experimental Data with EPA/OPPT/SAR Prediction on PPG Polymers

**J. S. Chun¹⁾, J. V. Nabholz²⁾, and M. J. Wilson²⁾ PPG
Industries, Inc., Pittsburgh, PA and US EPA, OPPTS,
Washington, DC.**

☰ Comparison of Environmental Fate Data from the PBT Profiler with Data Found in the Literature

**Dr. H. Burleigh-Flayer, PPG Industries, Inc., Pittsburgh,
PA.**

EPA Is Encouraging Risk Screening At R&D

EPA Provides

- 1. Powerful risk screening tools; the P2 Framework and PBT Profiler**
- 2. Training in the use, interpretation and limitations of EPA's screening methods**
- 3. Detailed, one-on-one, technical assistance: P2 Partnerships**
- 4. Regulatory Relief**
- 5. Small Business Assistance Program**

More Information on the P2 Framework

P2 Framework and Models Internet sites:

- www.epa.gov/oppt/p2framework
- www.pbtprofiler.net
- www.epa.gov/opptintr/exposure/
 - www.epa.gov/opptintr/exposure/docs/EPI_Suitedl.htm
 - www.epa.gov/opptintr/exposure/docs/efast.htm
 - www.epa.gov/opptintr/exposure/docs/chemsteer.htm

Call or email EPA contacts to:

- Request workshop information
- Ask additional questions

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