International Harmonization Efforts on Petroleum Substances

Characterizing Chemicals in Commerce: Using Data on High Production Volume (HPV) Chemicals
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Outline Of Talk

• Petroleum HPV Testing Group & Goals
• Harmonization of HPV Petroleum Categories
• GHS Classification and Labeling Of Petroleum Substances
  – IPIECA Proposal
  – CONCAWE Program
• Data Sharing For REACH
• Study Types And Data Sharing Limitations
Petroleum HPV Testing Group

• 60 Member Companies
  – American Petroleum Institute (Program Administrator)
  – Asphalt Institute
  – Gas Processors Association
  – National Petrochemical & Refiners Association

• Sponsor for 405 HPV Chemicals
Petroleum Industry Goals for Meeting the HPV Challenge

• Provide screening level hazard information as requested by USEPA – existing & new

• Generate Health, Environment, and Safety data (existing and new) in the US program for use in global voluntary and regulatory programs

• An example - LPG:
  • US HPV requirement = 28-day repeat-dose study
  • EU requirement = 90-day for RA
  • US program conduct 90-day study
  • Conserve technical, animal & financial resources
Strategy to Meet Goals

• Collaborate with domestic and global petroleum companies

• Coordinate EHS research efforts through petroleum industry trade associations
  – API - US
  – CONCAWE - Europe
  – IPIECA - global

• Form new collaborations with ICCA HPV program via ACC Petroleum-related Chemstar Panels
Petroleum Categories

- The Petroleum HPV Testing Group is using product-focused categories in the US program.
- Categories for petroleum substances were used before the US HPV Chemical Challenge Program.
  - European Union (EU) classification and labeling guidance under the Dangerous Substances Directive (DSD).
- Harmonized with EU by collapsing 37 EU categories into approximately a dozen categories.
US Petroleum HPV Product-Focused Categories

- Petroleum Gases (LPG)
- Gasoline
- Kerosene/Jet Fuel
- Gas Oils (Diesel #2 and Heating Fuel #2)
- Heavy Fuel Oils
- Lubricating Oils
- Aromatic Extracts
- Petroleum Waxes
- Asphalt
- Petroleum Coke
- Crude Oil
# HPV Categories/EU Categories

<table>
<thead>
<tr>
<th>HPV</th>
<th>EU DSD</th>
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<tbody>
<tr>
<td>Gas Oils (#2 diesel fuels/heating oils)</td>
<td>Straight Run Gas Oil Components</td>
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<tr>
<td></td>
<td>Cracked Gas Oil Components</td>
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<tr>
<td></td>
<td>Hydrocracked Gas Oil Components</td>
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<td></td>
<td>Vacuum Gas Oil Components</td>
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<td></td>
<td>Other Gas Oil Components</td>
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<td>Distillate Fuel Oils</td>
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Classification And Labeling Of Petroleum Substances

- Globally Harmonized System
  - United Nations guidance
  - Implemented by each country
- Petroleum industry efforts to globally harmonize classification include:
  - IPIECA for UN GHS worldwide
  - CONCAWE for EU GHS
EU REACH Requirements

REACH Requires Data Sharing
  – Mandates that manufacturer consortiums be formed
  – Requires “Letter Of Access” to use data sponsored by others
  – Having a copy of the study or a robust summary doesn’t mean you can use it to register under REACH
  – A REACH Implementation Project (RIP 3) is still working on guidance to industry on data sharing
Study Types And Sharing Limitations

Different Sources Of Data Change The Access To It:

– Petroleum HPV Testing Group sponsored studies (new data) will be made available for use in REACH

– API sponsored studies (existing data) will be made available for use in REACH

– Company studies submitted to the consortium to use in the HPV program (existing data) are still the property of the sponsoring company

  • Robust Summaries will be available
  • API will have copies of all studies if EPA wants to review
The petroleum industry is a global industry, so sharing HES data is an ongoing established practice.

Ongoing harmonization efforts include:
- HPV programs
- GHS
- REACH

The industry is committed to working with global regulatory agencies to satisfy their HES needs and requirements.
For more information

- http://www.epa.gov/HPV/
- Tom Gray: grayt@api.org
Acronyms

• ACC – American Chemistry Council
• ICCA – International Council of Chemical Associations
• CONCAWE - Conservation of Clean Air and Water in Europe
• IPIECA - International Petroleum Industry Environmental Conservation Association
• REACH – Registration, Evaluation, and Authorization Of Chemicals