

International Harmonization Efforts on Petroleum Substances

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

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Thomas M. Gray, M.S., D.A.B.T.
API Technical Manager, Petroleum HPV Testing Group

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

HPV

EU DSD

Gas Oils (#2 diesel fuels/heating oils)	Straight Run Gas Oil Components
	Cracked Gas Oil Components
	Hydrocracked Gas Oil Components
	Vacuum Gas Oil Components
	Other Gas Oil Components
	Distillate Fuel Oils

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

Summary and Conclusions

- 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