



GLOBAL CHEMICAL MANAGEMENT
API Supporting SAICM



American Petroleum Institute (API)

API is the only national trade association representing all facets of the oil and natural gas industry, which supports 9.8 million U.S. jobs and 8 percent of the U.S. economy. API's more than 625 members include large integrated companies, as well as exploration and production, refining, marketing, pipeline, and marine businesses, and service and supply firms. They provide most of the nation's energy and are backed by a growing grassroots movement of more than 25 million Americans.

www.api.org

Strategic Approach to International Chemicals Management (SAICM)

SAICM is a policy framework to promote chemical safety around the world. SAICM has as its overall objective the achievement of the sound management of chemicals throughout their lifecycle so that, by 2020, chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment. This "2020 goal" was adopted by the World Summit on Sustainable Development in 2002, as part of the Johannesburg Plan of Implementation.

www.saicm.org





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What is API?

The American Petroleum Institute (API) is the only national trade association representing all facets of the oil and natural gas industry, which supports 9.8 million U.S. jobs and 8 percent of the U.S. economy. API's more than 625 members include large integrated companies, as well as exploration and production, refining, marketing, pipeline, and marine businesses, and service and supply firms.

API conducts a variety of activities in addition to representing the oil and gas industry on public policy matters. For instance, API organizes seminars, workshops, conferences, and symposia on public policy issues. We conduct or sponsor research ranging from economic analyses to toxicological testing on petroleum chemicals. API collects and publishes statistics and data on all aspects of U.S. oil and gas industry operations, including supply and demand for various products, imports and exports, and industry activities and costs. For more than 80 years, API has led the development of petroleum and petrochemical equipment and operating standards. API maintains more than 600 standards, recommended practices, and technical reports, many of which have been incorporated into government regulations around the world. The American National Standards Institute (ANSI) accredits API's standards program. For many years, API licensed the International Organization for Standardization (ISO) to republish API standards as ISO publications. API also implements a certification program for manufacturers of equipment for petroleum production and refining.

Why is SAICM Relevant to API?

The United Nations Environment Programme (UNEP) Strategic Approach to International Chemicals Management (SAICM) is the main global forum to address chemical management issues. Petroleum and petroleum products—including but not limited to fuels—are chemical products, and many other downstream petrochemical products are derived from them. Furthermore, with recent innovation and growth in oil and gas exploration and production technologies, such as hydraulic fracturing, there is increased focus on chemical use in the petroleum industry. API's members are important participants in the global chemical supply chain—as producers, refiners, processors, distributors, and users of chemicals.

API and its members are dedicated to continuous efforts to meet chemical management responsibilities while economically developing energy resources and supplying high quality products and services to businesses, consumers, and governments. We recognize our responsibility to work with other industries, the public, government, and nongovernmental organizations to address potential risks that may arise during the lifecycle of our products and in our use of chemicals. Our efforts to manage chemical risks are directly aligned with SAICM's aim to mobilize resources to enhance the capacity of developing countries to manage chemicals while harmonizing chemical management policies globally.

API supports SAICM's central aim that chemicals should be manufactured, used, and managed safely at the international level in an efficient and cost-effective manner. API is contributing to the dialogue by developing industry positions on SAICM initiatives, coordinating with the U.S. Environmental Protection Agency (EPA) and multinational organizations, and contributing directly to the SAICM process as an important stakeholder in global chemical management.

API Activities Related to Chemical Management

API members' operations are global and cover every stage of the chemical lifecycle from research and development through production, use, and eventual disposition. API has established Environmental Principles that are a condition of membership, and these principles incorporate concepts of sound chemical management. Under API's Environmental Principles, API members pledge to manage their businesses using sound science to prioritize risks and to implement cost-effective management practices. The Environmental Principles are:

- To recognize and to respond to community concerns about our raw materials, products, and operations.
- To operate our plants and facilities and handle our raw materials and products in a manner that protects the environment and the safety and health of our employees and the public.
- To make safety, health, and environmental considerations a priority in our planning and our development of new products and processes.
- To advise promptly appropriate officials, employees, customers, and the public of information on significant industry-related safety, health, and environmental hazards, and to recommend protective measures.
- To counsel customers, transporters, and others in the safe use, transportation, and disposal of our raw materials, products, and waste materials.
- To economically develop and produce natural resources and to conserve those resources by using energy efficiently.
- To extend knowledge by conducting or supporting research on the safety, health, and environmental effectiveness of our raw material, products, processes, and waste materials.
- To commit to reduce overall emission and waste generation.
- To work with others to resolve problems created by handling and disposal of hazardous substances from our operations.
- To participate with government and others in creating responsible laws, regulations, and standards to safeguard the community, workplace, and environment.
- To promote these principles and practices by sharing experiences and offering assistance to others who produce, handle, use, transport, or dispose of similar raw materials, petroleum products, and wastes.

Each API member company implements programs appropriate to the particular company for pollution control, occupational health and safety, emergency response, transportation safety, chemical assessment, and other aspects of chemical management. Furthermore, many API members voluntarily engage in sustainability reporting based on the *Oil and Gas Industry Guidance on Voluntary Sustainability Reporting*,¹ which was developed by API, IOGP (the oil and gas industry association based in Europe) and IPIECA (the global oil and gas industry association for environmental and social issues). The Guidance allows for the reporting of sustainability indicators important to the oil and gas industry, as shown in **Table 1**.

The oil and natural gas industry was among the first business sectors to pioneer sustainability reporting. Individual company reporting provides detailed information in three areas: environmental performance, health and safety performance, and social and economic performance. Companies' individual sustainability reporting is usually available on their company websites for the public to view. In addition, many of our member companies are also members of the International Council of Chemical Associations (ICCA), and thus are participants in Responsible Care and the Global Product Strategy (GPS).

API supports member company activities in chemical management, and does work of its own related to chemical management. Below we discuss some of our specific activities related to chemical management, with examples for the Work Areas defined under SAICM.

Table 1 Indicators and Issue Categories

Issue	Indicator
Environmental Issues	
Climate change and energy	E1: Greenhouse gas emissions
	E2: Energy use
	E3: Alternative energy sources
	E4: Flared gas
Biodiversity and ecosystem services	E5: Biodiversity and ecosystem services
Water	E6: Fresh water
	E7: Discharges to water
Local environmental impact	E8: Other air emissions
	E9: Spills to the environment
	E10: Waste
	E11: Decommissioning
Health and Safety Issues	
Workforce protection	HS1: Workforce participation
	HS2: Workforce health
	HS3: Occupational injury and illness incidents
Product health, safety, and environmental risks	HS4: Product stewardship
Process safety and asset integrity	HS5: Process safety
Social and Economic Issues	
Community and society	SE1: Local community impacts and engagement
	SE2: Indigenous peoples
	SE3: Involuntary resettlement
	SE4: Social investment
Local content	SE5: Local content practices
	SE6: Local hiring practices and performance
	SE7: Local procurement and supplier development
Human rights	SE8: Human rights due diligence
	SE9: Human rights and suppliers
	SE10: Security and human rights
Business and transparency	SE11: Preventing corruption
	SE12: Preventing corruption involving business partners
	SE13: Transparency of payments to host governments
	SE14: Public advocacy and lobbying
Labor practices	SE15: Workforce diversity and inclusion
	SE16: Workforce engagement
	SE17: Workforce training and development
	SE18: Non-retaliation and grievance system

Examples of API Activities in SAICM Work Areas

The SAICM Global Plan of Action includes 36 work areas comprising almost 300 specific activities. The Work Areas cover virtually every aspect of chemical management, and API has a direct or indirect interest in virtually all of them. Selected SAICM Global Plan of Action Work Areas are listed below, with discussion of API activities in each area.



Assessment of National Chemicals Management

API is participating actively in the legislative process in the U.S. to develop a new chemical management law, and supports the effort to modernize the U.S. Toxic Substances Control Act (TSCA). For national chemical management laws, API supports a science and risk-based approach that includes working in partnership with other countries and harmonization, as appropriate. Since our member companies operate globally, they have expertise in the chemical management laws of the U.S., the European Union (EU), China, Japan, Korea, and other countries and regions.



Risk Assessment, Management, and Communication

Identifying and addressing potential risks associated with petroleum raw materials and products involves ongoing evaluation of their potential hazards and of the scenarios in which people and the environment may be exposed to them. Many of our member companies employ toxicology and industrial hygiene experts who identify the risks of their products, and ensure that risks are communicated and mitigated throughout the supply chain. The results of product risk assessment are incorporated into business decision making through workflow processes in which potential health, safety, and environmental impacts are identified and considered at each phase of product development.

In the EU, the petroleum trade association CONCAWE has a program for risk assessment of petroleum substances, including development of risk assessment methodologies to implement it. This includes PETRORISK, a spreadsheet tool, which performs environmental risk assessments for petroleum substances using principles provided by the European Chemical Agency (ECHA) for fulfilling stakeholder obligations under REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals). Many

API members participate in the program as part of their REACH compliance efforts.

In recent years, there has been a high level of innovation and economic growth underway in oil and gas exploration and production, including the deployment of advanced drilling techniques that use hydraulic fracturing. One important aspect of the petroleum industry's commitment to responsible and sustainable operations is assessing the potential health and environmental risks of chemicals used in hydraulic fracturing. Using available chemical assessment frameworks, oil and gas exploration and production service companies and operators have developed or adopted processes for assessing the potential health and environmental risks of the additives they use in hydraulic fracturing. These processes can be part of broader product stewardship programs, and some companies use them in research and development efforts to identify environmentally preferable products.

API supports transparency and risk communication through the disclosure of chemical substances used in hydraulic fracturing operations. One of the most important sources of this information is FracFocus.org, which was launched in 2011 by the Ground Water Protection Council and Interstate Oil and Gas Compact Commission. The information on FracFocus is constantly updated and currently comprises information from over 1,000 participating companies on over 91,000 wells in the U.S.² FracFocus is one of the largest single sources of publicly disclosed data on chemical usage of any industry in the world. Its online format and continuous updating make it a best practice for transparency and communication in chemical use.

API members are participating as stakeholders in government chemical management initiatives related to hydraulic fracturing. For example, in the EU, API members are participating in ongoing discussion about the possible development of generic exposure scenarios for substances used in hydraulic fracturing. These and other activities on chemical risk assessment for hydraulic fracturing provide a sound scientific foundation for risk assessment and communication regarding oil and gas production.

API recently developed a new document focusing on community. ANSI/API Bulletin 100 Part 3 – *Community Engagement Guidelines* serves as a gold standard for good neighbor policies that address community concerns, enhance the long-term benefits of local development, and ensure a two-way conversation regarding mutual goals for community growth. Released on July 9, 2014, Bulletin 100 Part 3 provides a detailed list of steps that oil and natural gas companies can take to help local leaders and residents prepare for energy exploration activities, minimize interruption to the community, and manage resources.³





Human Health Protection

Our member companies have environmental, health, and safety programs at production sites, refineries, storage facilities, distribution terminals, and all other company locations that involve chemical management. They implement comprehensive programs to prevent pollution and control emissions to air, water, and land. Over the years, our industry has established proven programs for pollution prevention, emergency preparedness and response, and community outreach.

API reports on expenditures by the U.S. oil and natural gas industry related to pollution prevention, control, abatement, or elimination in the United States and its territories.⁴ The U.S. oil and natural gas industry has invested over \$284 billion since 1990 toward improving the environmental performance of its products, facilities, and operations.

The oil and gas industry faces complex operating conditions that require evaluation of health, social, and environmental impacts throughout all of its operations. API supports efforts of the IOGP-IPIECA Health Committee, which has developed a guide on Health Impact Assessment (HIA)—a useful tool for business, communities, and government policymakers.

In our ongoing efforts toward continuous improvement of oil and natural gas operations, including ensuring protection of human health, in May of 2011, API completed a series of industry guidance documents pertinent to hydraulic fracturing:

- HF1, Hydraulic Fracturing Operations—Well Construction and Integrity;
- HF2, Water Management Associated with Hydraulic Fracturing Guidance;
- HF3, Practices for Mitigating Surface Impacts Associated With Hydraulic Fracturing;
- Standard 65-Part 2, Isolating Potential Flow Zones During Well Construction; and
- RP 51R, Environmental Protection for Onshore Oil and Gas production Operations and Leases.⁵

In 2013, HF1, HF2, and HF3 underwent a required review process, to reflect changes in industry operations and technological changes. All three documents are scheduled for release as revised recommended practices in September 2015.



Occupational Health and Safety

The petroleum industry has numerous programs to address the safety and health of workers, in all work environments. Petroleum companies have worker safety systems to comply with U.S. Occupational Safety and Health Administration (OSHA) and analogous requirements in other countries. Standard setting organizations such as American Conference of Industrial Hygienists (ACGIH) and the U.S. National Institute for Occupational Safety and Health (NIOSH) have developed standards, programs, and safe exposure limits for workers engaged in all aspects of the petroleum industry.

Hazard communication is a key component of an occupational health and safety program. U.S. petroleum companies have hazard communication programs to address requirements of the U.S. OSHA and various regulatory schemes around the world. Hazard communication in the workplace includes the elements presented in **Table 2**.

Table 2 U.S. Hazard Communication in the Workplace

Have a written hazard communication plan available to all employees.
Maintain a hazardous chemical inventory and a safety data sheet (SDS) for every hazardous chemical on site.
Ensure that each chemical container is labeled with the identity of the material and its hazard warnings.
Provide employees with information and training on the hazards of materials in their workplace.

Petroleum company safety data sheets (SDSs) may be authored by a multidisciplinary staff of experts in fields such as toxicology, industrial hygiene, environmental science, and regulatory compliance. They use scientific information to characterize the hazards of each material and to accurately communicate the associated warnings and precautions on the SDS. API member companies have central repositories of SDSs, which are used both at sites internal to the company and for providing SDSs to customers and other requestors. Hazard communication goes two ways—i.e., petroleum companies have systems for receiving, as well as distributing hazard information. Major petroleum companies have processes for receiving, evaluating, and responding to incident reports or any new health, safety, or environmental information about their products.

Some petroleum companies produce hazard summary documents that supplement the required SDS. These summary documents may highlight key points such as required personal protective equipment and what to do in case of a spill. Some of our member companies follow the International Programme on Chemical Safety to promote the use of International Chemical Safety Cards (ICSCs). An ICSC includes standard phrases summarizing health and safety information, which are verified and peer reviewed by internationally recognized experts and take into account advice from manufacturers and Poison Control Centers.

The IOGP and IPIECA *Guide to Health Impact Assessments in the Oil and Gas Industry* recommends a systematic approach to protecting workers' health. IOGP and IPIECA have developed an assessment process designed to help employers identify, measure, and deal with health risks. The committee has also produced a set of performance indicators for promoting employee health.

To enhance safety and improve process safety performance, API and American Fuels and Petrochemicals Association (AFPM, formerly NPRA) offer programs to further advance process safety improvements by providing industry with more opportunities to communicate and share experiences and knowledge – vital components of the industry's commitment to improve process safety performance. These include process safety performance metrics, site assessments, regional networks, event sharing, and hazards identification.



Implementation of GHS

API actively supports implementation of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) as adopted by individual countries. Companies have addressed GHS implementation requirements in keeping with adoption of GHS into the legal frameworks of various countries. As recent examples, in 2012 the U.S. OSHA published a revised Hazard Communication Standard (HCS) to implement GHS, and in 2015, Health Canada published Hazardous Products Regulations to implement GHS. API members worked to produce labels and SDSs consistent with the revised provisions in these and other countries.

To facilitate appropriate classification and labeling of petroleum substances, including crude oil, API with IPIECA has developed guidance on the application of the GHS to petroleum substances, in consultation with the UN Subcommittee of Experts on the GHS. The IPIECA *Guidance on the Application of Globally Harmonized System (GHS) Criteria to Petroleum Substances*⁶ identifies representative constituents of concern for crude oil, for example, hydrogen sulfide, benzene, and PACs. It helps the user understand the GHS criteria needed to meet national and international standards for classification and labeling. From there, appropriate risk management actions can be designed to minimize human health risks from potential exposure to crude oil and other petroleum substances. This guidance seeks to facilitate appropriate classification and labeling of petroleum substances around the globe.

API also has worked with international organizations such as the International Maritime Organization (IMO) and the Asia Pacific Economic Cooperation (APEC) Chemical Dialogue to support harmonized hazard communication requirements in general and GHS implementation in particular.





**API AND ITS MEMBERS
HAVE CONDUCTED
THOUSANDS OF STUDIES
OF POTENTIAL HUMAN
AND ENVIRONMENTAL
HAZARDS ASSOCIATED
WITH DRILLING,
MANUFACTURING, AND
USE OF PETROLEUM
PRODUCTS**





Cleaner Production

API and its members continually strive to minimize the health and environmental impacts of oil and gas production, and to produce cleaner-burning fuels that result in cleaner production in global industry. There are about a million oil and natural gas wells operating in the U.S. Advancements in technology allow our members to conduct many aspects of production operations far more efficiently than just a few years ago, which means smaller “footprints” (the amount of surface area disturbed), less waste generated, cleaner and safer operations, and reduced impact on the environment. Today’s oil and gas producers are applying a host of new technologies and strategies to minimize the environmental impact of their operations.

Technological advances in production of natural gas are making a huge contribution to the ability of other industries, including electric utilities, to achieve cleaner production. Recent innovations have unlocked vast new supplies of natural gas, which burns cleaner and more efficiently than alternatives.

Many of our member companies are investing in active research and development of products with potential environmental benefits, e.g., biofuels, alternate sources of fuels, environmentally preferable solvents and other products, and environmentally preferable chemicals for use in petroleum operations such as hydraulic fracturing. Petroleum company scientists are well-positioned to contribute to the next generation of energy and chemical innovations that enable sustainable product solutions.



Lead in Gasoline

In 1995, petroleum companies completed the removal of lead from gasoline in the U.S. Petroleum companies have removed lead from gasoline in more than 175 countries worldwide—representing near-global elimination of lead in motor vehicle gasoline. API is a member of IPIECA, a founding member of the international Partnership for Clean Fuels and Vehicles, which is helping developing countries eliminate lead from gasoline, reduce sulfur levels in transportation fuels, and introduce cleaner motor vehicles that use these fuels.

The petroleum industry is also working on removal of lead from aviation fuels. For instance, the Piston Aviation Fuels Initiative (PAFI) is an industry-government program designed to facilitate the development and deployment of an unleaded aviation fuel with the least impact on the existing piston-engine aircraft fleet. The primary objective is for the U.S. Federal Aviation Administration (FAA) to issue a fleet-wide approval for the most viable replacement fuels. The FAA and six trade associations, including API and aircraft industry associations, are working together on the project.



PBTs and Other Chemicals of Concern

API’s member companies have experience addressing issues related to toxic chemicals such as persistent, bioaccumulative, toxic (PBT) chemicals and other chemicals of global concern. Air pollution prevention and mitigation efforts are key activities where chemical concerns are addressed because many of the chemicals of global concern have the potential to be air pollutants. Advances by API companies in the U.S. in reducing toxic air pollutants have been made as the industry has addressed regulations under the U.S. Clean Air Act. In the 1990 Amendments to the U.S. Clean Air Act, provisions were added to regulate the emissions of 188 hazardous air pollutants (HAPs) from stationary and mobile sources.

The oil and natural gas industry is covered by a large number of regulations, tailored to specific industry categories, or source categories. For instance, the industry is subject to MACT rules to reduce HAP emissions for source categories including hazardous organics; gasoline distribution; marine vessel loading operations; petroleum refineries; natural gas transmission and storage; site remediation; organic liquids distribution; reciprocating internal combustion engines; industrial, commercial, and institutional boilers and process heaters; and combustion turbines.





**OUR MEMBERS OPERATE
UNDER THE VARIOUS
REGULATORY SCHEMES
AROUND THE WORLD FOR
PREVENTION OF AND
RESPONDING TO CHEMICAL
EMERGENCIES.**



Waste Management (and Minimization)

Responsible waste treatment, storage, and disposal is a given for our member companies. In addition, waste minimization—including extensive reuse and recycling—is a key component of petroleum production and refining operations. Petroleum companies maximize product recycling and encourage others in the value chain to do so as well. Some companies conduct research to extend product life—which means less waste is generated and, for fuels, energy consumption is reduced. Petroleum companies routinely provide instructions for proper disposal to customers on SDSs and other materials.

Used oil collection and recycling is an important example of our industry's effectiveness at waste minimization and recycling. Most people are familiar with recycling newspapers, aluminum cans, glass, and plastic, but may not be aware of the efforts of the petroleum industry to promote recycling of used motor oil. API reminds consumers and industry to recycle used motor oil, thereby keeping it out of waterways and ground water supplies. Additionally, we provide educational materials on how to recycle used oil.



Remediation of Contaminated Sites

Petroleum companies have been involved in many successful remediation projects and have expertise in the most current remediation technologies. One example of collective involvement in this issue was the Total Petroleum Hydrocarbon Criteria Working Group, which was formed as a voluntary initiative of industry and other stakeholders to develop a set of clear, science-based, health benchmarks for use during cleanup at sites with petroleum/hydrocarbon contamination. The Working Group was formed to address the use of diverging cleanup requirements by various federal, state, and local agencies in the U.S. The Working Group was guided by a steering committee consisting of representatives from industry, government, and academia.



Prevention and Response for Emergencies Involving Chemicals

Petroleum industry best practices include operating procedures and employee training to manage risk through storage, handling, transportation, and distribution of our raw materials and products. Because of the flammable nature of many petroleum products, safety and risk management have always been essential components of storage and handling. These safe practices also mitigate health and environmental hazards.

It is a fundamental business objective to maintain petroleum product integrity through the whole chain of custody of a product. Thus, many petroleum companies have strict requirements for distributors that cover both product quality and facility conditions. Some companies implement facility assessment programs to ensure that products are handled properly at all points from the refinery to eventual delivery to the end user. These controls during storage and distribution serve to prevent potential emergencies involving our products.

Many petroleum companies are members of Chemtrec, which was established in 1971 by the chemical industry as a public service hotline for emergency responders, such as fire fighters and law enforcement, to obtain information and assistance for emergency incidents involving chemicals and hazardous materials. Oil transportation companies in the U.S. have developed oil spill response co-ops known as Oil Spill Removal Organizations (OSROs). These organizations, on contract with oil companies, provide equipment, personnel, and the skills needed to respond to an oil spill.

Our members operate under the various regulatory schemes around the world for prevention of and response to chemical emergencies. For example, under oil pollution prevention regulations in the U.S., petroleum facilities prepare and implement programs for preparing for and responding to a worst case discharge. As another example, many petroleum facilities must comply with the chemical accident prevention provisions of the U.S. Clean Air Act. These provisions require a risk management program, and aim to prevent accidental releases of substances that could cause serious harm to the public and environment from short-term exposures, and to mitigate the severity of releases that may occur.

Consistent with transportation requirements in the U.S. and other countries, petroleum companies implement programs to mitigate the risks to life, property, and the environment inherent in the transportation of hazardous materials, by strategies related to shipping papers, packaging materials, hazard communication, safe handling, incident reporting, training, and security. Numerous standards, including API standards, have been developed to cover all aspects of gasoline storage, transport, and handling. These standards cover the design, construction, and operation of virtually every piece of equipment from above ground and underground storage tanks, to piping, terminals and loading racks, to tank trucks, rail cars, and barges.



Pollutant Release and Transfer Registers (PRTRs)

Petroleum refineries, bulk stations, and terminals have extensive experience with PRTR-type reporting under U.S. Toxics Release Inventory (TRI) requirements, which instituted the first PRTR in the world. Petroleum facilities in subject sectors in the U.S. file annual TRI reports, and have been stakeholders in the TRI program since its inception. API supports the community's right to know about chemical releases, and our members actively work to minimize waste and releases. Our member companies have valuable insight on the practical application of PRTRs and ideas for how to maximize their accuracy and effectiveness.



Lifecycle

The petroleum industry has experience using the lifecycle management concept as a tool in risk assessment and product stewardship. The first stage in the life of a petroleum product is exploration and production, in which crude oil is drilled from land wells or offshore. This exploration and production occurs in many countries around the world. In the U.S., crude oil is processed in one of the nation's 140 refineries, which process more than 15 million barrels of crude oil every day into hundreds of products including gasoline, heating oil, diesel fuel, engine oils, jet fuel, kerosene, and many others. Petroleum products are distributed by rail, road, water, or pipeline through distribution terminals and storage facilities to the U.S. and to other countries.

Eventual destinations for petroleum products include service stations, homes, and direct-served users such as airports. Some refinery outputs are intermediate products that are used to manufacture other products—petroleum serves as the feedstock for production of diverse petrochemicals which support solutions for a healthy and plentiful food supply, clean air and water, safe and comfortable living conditions, efficient and affordable energy sources, and lifesaving medical treatments in communities around the world. (Many petroleum products do not have a disposal phase because they are burned as fuel, but others, e.g., oils, do have a post-use stage in which the product or its residuals are treated, recycled, and/or disposed.)

API and its members have expertise on chemical lifecycle issues. We are unique as a trade association in the scope and variety of global activities our members undertake—from drilling crude oil and natural gas, to refining them into various petroleum products, to the distribution and sale of our products.



Hazard Data Generation and Availability

API has a long history of accomplishments in the SAICM Work Area of *hazard data generation and availability*. API has conducted toxicity, exposure, and environmental studies on petroleum substances since the 1950s. API and its members have conducted thousands of studies of potential human and environmental hazards associated with drilling, manufacturing, and use of petroleum products. This hazard information is used by industry as well as government agencies to protect human health and the environment during all aspects of the manufacture and use of petroleum products.

API generates hazard data in direct response to government regulation. However, a much larger proportion of API research is conducted voluntarily as part of product stewardship and overall risk management efforts. API provides regulators and the public with safety information on petroleum products—which range from small amounts of highly refined products used as food additives and food packaging to a large volume of fuels to asphalt used to pave road surfaces. API provides the scientific information it generates to government and standards organizations to support development of ACGIH exposure guidelines, U.S. OSHA exposure limits, Integrated Risk Information System (IRIS) profiles, and other reference and regulatory levels.



Many API studies are publicly available through an extensive publications catalog available online (<http://www.api.org/Publications/>), in the API Toxicology Database, (<http://apitox.api.org/>), and on the U.S. EPA's website (<http://www.epa.gov/HPV/pubs/general/hpvchemdata.htm>). API also encourages publication of API-sponsored research in peer-reviewed journals. Examples of some API accomplishments in the areas of hazard data generation are summarized below.



information on its physical and chemical properties, health and environmental hazards, and environmental fate, as well as providing summaries of this information to EPA and the public. The challenge program also called for identifying data gaps in knowledge about specific chemicals and submitting test plans for conducting additional hazard testing to fill the gaps. The aim was to fulfill the data requirements of the Organization for Economic Cooperation and Development (OECD) for its Screening Information Data Set (SIDS), which includes physical/chemical properties, environmental fate and toxicity, and mammalian toxicology endpoints.

The oil and gas industry sponsored nearly 400 of the total 1400 substances that were directly sponsored by chemical manufacturers in the HPV program. The industry formed and managed the Petroleum High Production Volume Testing Group (PHPVTG), comprised of 70 member companies from API, the AFPM, the Gas Producers Association (GPA), and the Asphalt Institute.

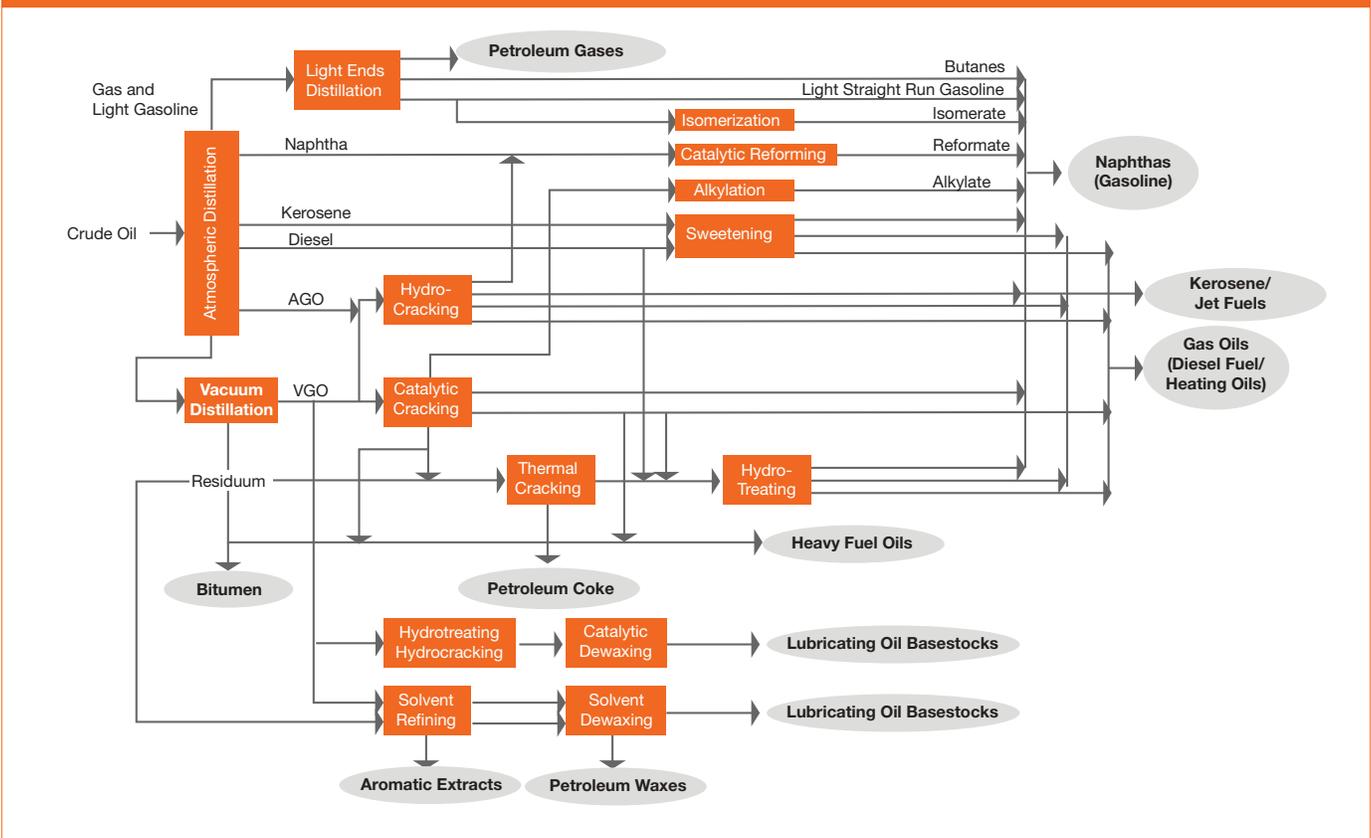
High Production Volume Chemical Program

The U.S. High Production Volume (HPV) Chemical Challenge program responded to a “challenge” issued by the U.S. EPA to chemical manufacturers in 1998, to “sponsor” chemicals manufactured or imported in the U.S. in total quantities over one million pounds per year. Sponsorship of a chemical entailed collecting and summarizing

Despite their chemical complexity, petroleum substances have many similarities that largely result in similar toxicological profiles. Therefore, it was scientifically appropriate to group petroleum streams into product groups or “categories” to maximize the utility of existing data and minimize the extent of additional animal testing required.

Figure 1 shows the petroleum categories.

Figure 1 Refinery Processes and Categories - PETROLEUM CATEGORIES





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**API WITH IPIECA
HAS DEVELOPED
GUIDANCE ON THE
APPLICATION OF THE
GHS TO PETROLEUM
SUBSTANCES**
”



The HPV challenge program addressed properties including acute toxicity, repeated dose toxicity, in vitro and in vivo genetic toxicity, as well as developmental and reproductive toxicity. Information addressing other toxicological hazards was compiled and summarized when available. **Table 3** summarizes the types of testing that were conducted for each of the categories of petroleum substances. In some cases, the review of the existing data did not identify any gaps that needed to be addressed with additional testing.

The results of the PHPVTG efforts are contained in Category Assessment Documents, which API submitted to EPA for review and comment. These and other documents are available to the general public from API (www.petroleumhvp.org). In addition, much of this work has been published in peer-reviewed journals.

Table 3 Number of Substances in Product Categories and Summary of Testing Conducted

Substance Category	Substance ^a	RDTax ^b	Rep/Dev ^c	Genetox ^d	Env Tox ^e
Aromatic Extracts	6	X	X	X	
Asphalt	6	X	X	X	
Crude Oil	1	No testing recommended			
Gas Oils	28	X	X		X
Gasoline	81		X		X
Grease Thickeners	11				
Heavy Fuel Oils	32	X	X		
Kerosenes	6	X			X
Lubricating Oils	34	X	X		
Petroleum Coke	2		X		X
Petroleum Gases	161	X	X	X	
Reclaimed Substances	10		X		X
Waxes	8	No testing recommended			

^a Approximate number of substances in category
^b 90-day repeat dose toxicity study
^c Reproductive and/or developmental toxicity study
^d Genetic toxicity study
^e Environmental fate and/or toxicity studies

Benzene Research

For over 30 years, the petroleum industry has supported scientific research to understand the effects of benzene. Our research has included epidemiological studies of occupationally exposed individuals to estimate the risk of exposure to benzene, which has been associated with leukemia. These estimates have been used by regulatory agencies to set exposure limits to protect workers and the public.

Using state-of-the-art biomedical equipment and techniques, scientists supported by grants from API and individual petroleum companies have worked to unravel the biochemical mechanisms that can result in the initiation of leukemia. The petroleum industry research program has included delineating the metabolism of benzene, building a mathematical model of how benzene and its metabolites move through the body, and working to determine how the risk of hematopoietic disease changes as exposures become very small.

The benzene research program includes work to understand the mechanism by which exposure to sufficiently high amounts of benzene can result in acute nonlymphocytic leukemia (ANLL), myelodysplastic syndromes (MDS), and bone marrow depression. An early epidemiology study showed a cohort of rubber workers who had high exposures to benzene and an increased mortality from ANLL. The API program attempted to refine the risk estimates by funding a reexamination of the original exposure estimates using Monte Carlo techniques, and recalculating risk using alternative epidemiological techniques. The research program also included measuring the metabolism of benzene at low exposures, and developing a PBPK model of formation and distribution of metabolites in animals and humans. A mathematical model was developed to predict benzene-induced bone marrow toxicity in experimental animals. The research program continues today to further study the biological mechanism by which benzene may affect the bone marrow to result in cytotoxicity and potentially ANLL or MDS.

Since 1990, the benzene research program has resulted in dozens of peer-reviewed papers published in scientific journals. Understanding the risk of benzene exposure over a wide range allows better protection of workers and the public from benzene exposure. API continues its relationship with other industry groups such as CONCAWE in these efforts.

Naphthalene Research

Naphthalene (NA) research is another example of how the petroleum industry has participated in an extensive research program to understand human health risks from exposure to a chemical found in our industry's products and process streams. Naphthalene—which is found in gasoline, diesel fuel, jet fuel, and asphalt—was classified as a possible human carcinogen by the International Agency for Research on Cancer (IARC) based on a rodent cancer study. Joining with other associations from the railroad, asphalt, and chemical industries, API participated in a six-year research program to understand the biological mechanism of nasal tumor formation in rodents and the relevance of that mechanism to humans exposed to naphthalene.

A team of respected researchers, many of them academics, investigated the nasal tumor phenomenon. Metabolism studies determined that naphthalene metabolism in rats is not predictive for its metabolism in humans. Gene activation studies verified that nasal cytotoxicity only occurred at high concentrations such as those used in early inhalation cancer studies. Gene expression studies supported the linkage of cytotoxicity to a metabolite, not NA. Other researchers developed a mathematical (PB-PK) model to simulate naphthalene pharmacokinetics in humans, as well as nasal airflow patterns in rats and humans. This research program has been summarized using a weight-of-evidence approach and published in a peer-reviewed toxicology journal. Risk assessment based upon this research program provides a sound basis for estimating human cancer risk from inhalation of NA and ensuring that human health will be adequately protected.

TAME Research

API and individual member companies have conducted extensive research on tertiary amyl methyl ether (TAME), which is one of the aliphatic ethers that has been used as a gasoline additive. Studies were conducted both voluntarily by API or individual API members and under an agreement with the U.S. EPA. The work included numerous mammalian and ecotoxicity studies such as studies of acute toxicity, mutagenicity, developmental toxicity, reproductive toxicity, neurotoxicity, dermal sensitization, aquatic toxicity, and others. These studies are a substantial contribution to the science to characterize hazards of TAME.

API Petroleum Streams Program

In the late 1970s, API and its members recognized the need for hazard data on petroleum streams generated in refineries, which are blended into petroleum products such as gasoline, kerosene, lube oils, and heavier fuel oils. To this end, API collected 28 petroleum stream samples from US refineries across the country. The samples represented typical refining processes including various processed and straight and cracked run naphthas, kerosene, straight and cracked run middle distillates, vacuum residuals, and catalytically cracked clarified oils.

All of the samples were subjected to analytical tests for hydrocarbon type, polynuclear aromatic analysis, and additional detailed constituent analysis by gas chromatography/ mass spectroscopy. The representative streams were then subject to a standard battery of toxicity testing using oral, dermal, and inhalation exposure routes depending on the type of test and volatility of the stream being tested. The toxicity tests evaluated the potential of the various streams to cause acute, subchronic, or chronic health effects, dermal carcinogenicity, or mutagenic toxicities. The streams also were tested for potential eye and skin irritation and dermal sensitization. If results of concern were observed in the routine battery of testing, streams or analogous streams underwent further testing. Other streams were evaluated to investigate other endpoints of interest such as developmental and/or reproductive toxicity.

Several API member companies created a program similar to the API Petroleum Streams Program to supplement data for selected petroleum streams with additional mammalian toxicity data (subchronic, reproductive and/or developmental toxicity and/or neurotoxicity testing), as well as a standard battery of five acute ecotoxicity tests in aquatic vertebrates, invertebrates, and plants.

Other Hazard Data Programs

API and its members have completed many other hazard data generation projects. Some examples are presented in **Table 4**.

In the EU, the petroleum trade association CONCAWE carries out research to improve scientific understanding of the environmental, health, safety, and economic performance aspects of both petroleum refining and the distribution and sustainable use of refined products. CONCAWE has been assisting its members in preparation of the joint parts of REACH registration dossiers and enabling its members to join together in sharing the costs of conducting studies necessary to register substances under REACH. CONCAWE has developed PETROTOX, a spreadsheet model, designed to calculate the toxicity of petroleum products to aquatic organisms. Many of API's member companies participate in efforts such as those of CONCAWE and do their own work to develop health and safety data on chemical substances for purposes of REACH registration.

The international nature of the trade and commerce of petroleum makes SAICM an important issue for API and our members. We have a long history understanding and addressing the various chemical management issues that are inherent in our fundamental business activities. API remains supportive of the SAICM process, and we hope our knowledge and experience will continue to make a valuable contribution to the Strategic Approach.



Table 4 Examples of Other API Hazard Data Generation Programs

API Program	Types of Tests and Activities for Program
Clean Air Act Section 211(b)	<ul style="list-style-type: none"> • Comprehensive literature review (over 12 volumes of abstracts) on the health effects of gasoline, known constituents of gasoline, and six oxygenate ether or alcohol oxygenate additives. • Extensive public exposure studies in multiple exposure scenarios. • Comparative toxicology testing of gasoline and oxygenate-gasoline, including testing for potential carcinogenicity, reproductive and developmental toxicity, subchronic toxicity, and other toxicological endpoints.
Synthetic Drilling Muds Program	<ul style="list-style-type: none"> • Examined the environmental impacts of synthetic muds used during offshore drilling. • Included field study of the deposition of muds on the ocean bottom and developing tests for biodegradation and toxicity.
White Oils and Waxes Program	<ul style="list-style-type: none"> • Research program to reaffirm the safety of highly refined food grade petroleum-derived oils and waxes, conducted in collaboration with CONCAWE, to address regulatory concerns in the EU. • Included species and strain comparisons, summary of all previous literature on the substances, extensive human population exposure studies in both U.S. and European populations, and multiple subchronic and chronic toxicity studies, and evaluation of immunotoxicity potential. • Pathology review workshop included international experts in the field of liver toxicity.
Hydrogen Sulfide	<ul style="list-style-type: none"> • API helped sponsor key studies on hydrogen sulfide including evaluation of potential neurological effects, biochemical effects on tissues including the brain, and sensory and cognitive effect of acute low level exposure in humans.
Commercial Hexane	<ul style="list-style-type: none"> • Numerous in-depth toxicity studies.
Petroleum Product or Constituents	<ul style="list-style-type: none"> • Literature reviews and studies on major products such as gasoline, gasoline exhaust, jet fuel, and lubricating oils. • Literature reviews and studies on single compounds including benzo(a)pyrene, butane, ethanol, n-hexane, xylene and mixed xylenes, and heavy metals (e.g., cadmium, zinc). • Toxicity studies including acute, subchronic, chronic, dermal irritation and sensitivity, genotoxicity, reproductive and developmental, carcinogenicity, pharmacokinetic, and mechanistic studies. • Also included human biomonitoring (e.g., carboxyhemoglobin as a marker for exhaust-related carbon monoxide), exposure studies, and environmental fate and ecotoxicity testing.

References

¹ IPIECA, API, and IOGP. Oil and Gas Industry Guidance on Voluntary Sustainability Reporting (3rd edition), 2015.

<http://www.ipieca.org/publication/oil-and-gas-industry-guidance-voluntary-sustainability-reporting-3rd-edition>.

² FracFocus-style disclosure is also in use in other countries such as Canada.

³ The document is available on API's website via this link: <http://www.api.org/news-and-media/news/newsitems/2014/july-2014/api-issues-good-neighbor-standards-for-oil-and-natural-gas-developers>.

⁴ American Petroleum Institute. Environmental Expenditures by the U.S. Oil and Natural Gas Industry 1990 – 2014, 2014.

⁵ The “HF Series” (HF1, HF2, HF3) provides an important complement to two other recommended practices – Standard 65 Part 2, which ensures multiple levels of protection between sources of drinking water and the production zone of an oil and gas well and RP 51R, which provides recommendations to reduce the environmental footprint at exploration and production sites.

⁶ IPIECA. Guidance on the Application of Globally Harmonized System (GHS) Criteria to Petroleum Substances. Version 1, 17 June 2012. See <http://www.ipieca.org/publication/guidance-application-globally-harmonized-system-ghs-criteria-petroleum-substances>.



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