Under Section 211(b) of the Clean Air Act, manufacturers and importers of fuel and fuel additive products must register them with the U.S. Environmental Protection Agency (EPA) before offering the products for sale. The 211(b) Research Group, managed by the American Petroleum Institute (API), was formed to fulfill 211(b) testing requirements for gasoline and diesel fuel. This conference marks over 25 years of effort to fulfill the testing requirements and offers the opportunity to review the program, its results, and current status of health effects testing and risk assessment for fuels.

MARCH 24, 2020

WELCOME AND INTRODUCTIONS
Derek Swick, American Petroleum Institute

REGULATORY DRIVERS FOR TESTING MANDATE
Maryam Hatcher, American Petroleum Institute (Moderator)
Joshua H. Van Eaton, Beveridge & Diamond PC

Clean Air Act Section 211(b)(2) gave EPA the authority to mandate testing of fuels and fuel additives, with a focus on exhaust and evaporative emissions. EPA issued an implementing rule in 1994. This session will review relevant provisions of the Clean Air Act and regulations in 40 CFR Part 79. It will explain how the tiered testing requirements are structured, the information that producers of motor vehicle fuels and fuel additives are required to provide, and other aspects of how the requirements work.

EVOLUTION OF 211(b) RESEARCH GROUP PANEL
Derek Swick, American Petroleum Institute (Moderator)
Bob Wilkenfeld
Dave Steup

To fulfill the 211(b) requirements, API organized the 211(b) Research Group, an unincorporated group of over 200 fuel, oxygenate, and fuel additive manufacturers. This session will cover the history of the group, which includes Oversight and Technical Committees staffed by member company representatives. The presentation will discuss the composition and role of the membership, the different sub-workgroups for the various study types, and the role of API staff.
GENERATION AND CHARACTERIZATION OF TESTING MATERIALS AND NEGOTIATIONS WITH EPA

Jessica Ryman-Rasmussen, American Petroleum Institute
Linda Roberts

This session will describe the extensive research involved in designing a method to generate and characterize the evaporative emissions used in toxicology studies for the 211(b) testing program. The 211(b) Research Group developed a method for generating test substances that best represented real-world evaporative emissions and the Group worked to obtain Agency approval for the proposed approach.

LOGISTICS AND GLP COMPLIANCE

Christina Sexsmith, Sexsmith Consulting Services LLC

This session will explore the acquisition, distribution, inventory, analysis, and disposal of test material; development and review of detailed study protocols; monitoring of ongoing studies; and the flow of work product through the process of review by EPA as well as API and the 211(b) task force. Study material maintenance, disposal, and inventory will also be examined. Good Laboratory Practice (GLP) compliance for the duration of the 211(b) program will be discussed, including API responsibilities and the role of contract laboratories.

TIER II PROGRAM TESTING REQUIREMENTS

Rich Clark

In response to EPA’s Tier II requirements for health effects testing on diesel and gasoline engine exhaust emissions, as well as on gasoline evaporative emissions, the 211(b) Research Group sought modifications to address the many issues associated with performing the tests. This session will review how the Research Group sponsored research and literature searches and worked with EPA toward practical requirements for the Tier II testing program.

HEALTH EFFECTS PANEL

Katherine Kraft, Chevron (Moderator)
Linda Roberts, Napatox Consulting LLC
Rich Clark
Ceinwen Schreiner
Bob Wilkenfeld

This session presents the hazard characterization research conducted in Tier II. It will discuss test materials, study design, experimental observations, and conclusions of health effects research including:

- Developmental toxicity studies in rats and mice;
- Subchronic toxicity studies;
- Two generation reproductive toxicity studies;
- Neurotoxicity evaluations;
- Genotoxicity evaluations;
- Carcinogenicity; and
• Immunotoxicity evaluations.

RECEPTION
The first day will close with a chance to network and relax with colleagues at a reception.

MARCH 25, 2020

POPULATION EXPOSURE STUDIES
Dave Campbell, DRI
This presentation will review the objectives, design, and results of the 211(B) Tier II *High End Exposure Study of Conventional and Oxygenated Gasoline* conducted by the Desert Research Institute and will discuss how well its objectives were met.

PHARMACOKINETICS PANEL
Linda Roberts, Napatox Consulting LLC
Dave Steup
This session will review the methodologies and results for three toxicokinetic studies of potential gasoline oxygenate additives.

MOBILE SOURCE AIR POLLUTANTS IN URBAN MICROENVIRONMENTS
Dave Campbell, DRI
This presentation will describe research done after the *High End Exposure Study*, including the API-funded Exposure classification project—Concentrations of mobile source air pollutants in urban microenvironments. It will outline the design and results of the studies and implications for exposure assessment methods. There will be discussion on how current monitoring technology could be used to address questions not fully answered by prior studies.

PUBLIC DISSEMINATION OF STUDY RESULTS
Derek Swick, American Petroleum Institute
This session will review industry efforts to disseminate science generated from the 211(b) program, including journal publications and conference presentations.

ALTERNATIVE JET FUELS PANEL
Jessica Ryman-Rasmussen, American Petroleum Institute (Moderator)
Dave Mattie
Brian Wong
Andrew J. Keebaugh
This session will include an overview, panel discussions pertaining to specific alternative jet fuels, and a Q&A session on work to address alternative jet fuels. A panel will address U.S. Department
of Defense (DOD) alternative jet fuels inhalation studies. Alternative jet fuels to be addressed by the panel include Synthetic Paraffinic Kerosene (SPK) jet fuel generated by Fischer–Tropsch (FT) process, Hydrosprocessed Esters and Fatty Acids (HEFA), camelina plant oil, rendered animal fat (tallow) and mixed fats and oils, Gevo Low Carbon Renewable Jet Fuel, and Amryis, Inc. farnesane made by direct sugar-to-hydrocarbon process.

TIER 3
TBD

This session will discuss the possibility of additional testing in a Tier III. It will discuss the type of studies that could be triggered by Tier II results and whether there is a need for them.

WRAP UP
Derek Swick, American Petroleum Institute

The conference will wrap up with a discussion of the current status of the 211(b) Research Group, including whether it should continue and in what form.

CLOSED PANEL: LESSONS LEARNED AND RECEPTION
RESEARCH GROUP
MEMBERS ONLY
Katherine Kraft, Chevron

A closed panel will discuss key lessons learned from industry experience with this major testing program, including issues related to the operation of the Research Group and API’s administration of it.