

EPA Registration and Health Testing Requirements for Diesel Blends



**CEC Alternative Diesel Diesel Fuel Symposium
Sacramento, CA August 19-20, 2003**

Presented by Dave Kortum

U.S. EPA Office of Transportation and Air Quality

Organization of Presentation



- What is required?
- What is the purpose of the requirements?
- Who is affected/does the testing?
- What testing is performed? Diesel-Specific Testing Issues
- Conclusion

Fuels/Fuel Additives (F/FA) Registration

- Under the Clean Air Act, all gasoline and diesel motor fuels and additives must be registered to assure
 - That health testing is completed and
 - Illegal or damaging additives are not introduced into commerce.
- Registrations are, in effect, licenses to introduce F/FA into commerce

Rule Finalized in May, 1994



- To screen for potential health effects of emissions of fuels/fuel additives (F/FAs)
- Testing evaluates the effects of inhalation exposure to the whole complex emission mixtures, not toxicology of individual pure compounds.

Who is Affected?



- Manufacturers of gasoline and diesel F/FAs for on-road use -- designed for highways and city streets.
- For existing F/FAs, testing must be performed to retain registration (license to introduce)
- For new F/FAs unable to group with existing F/FAs, testing must be completed before introduction into commerce.

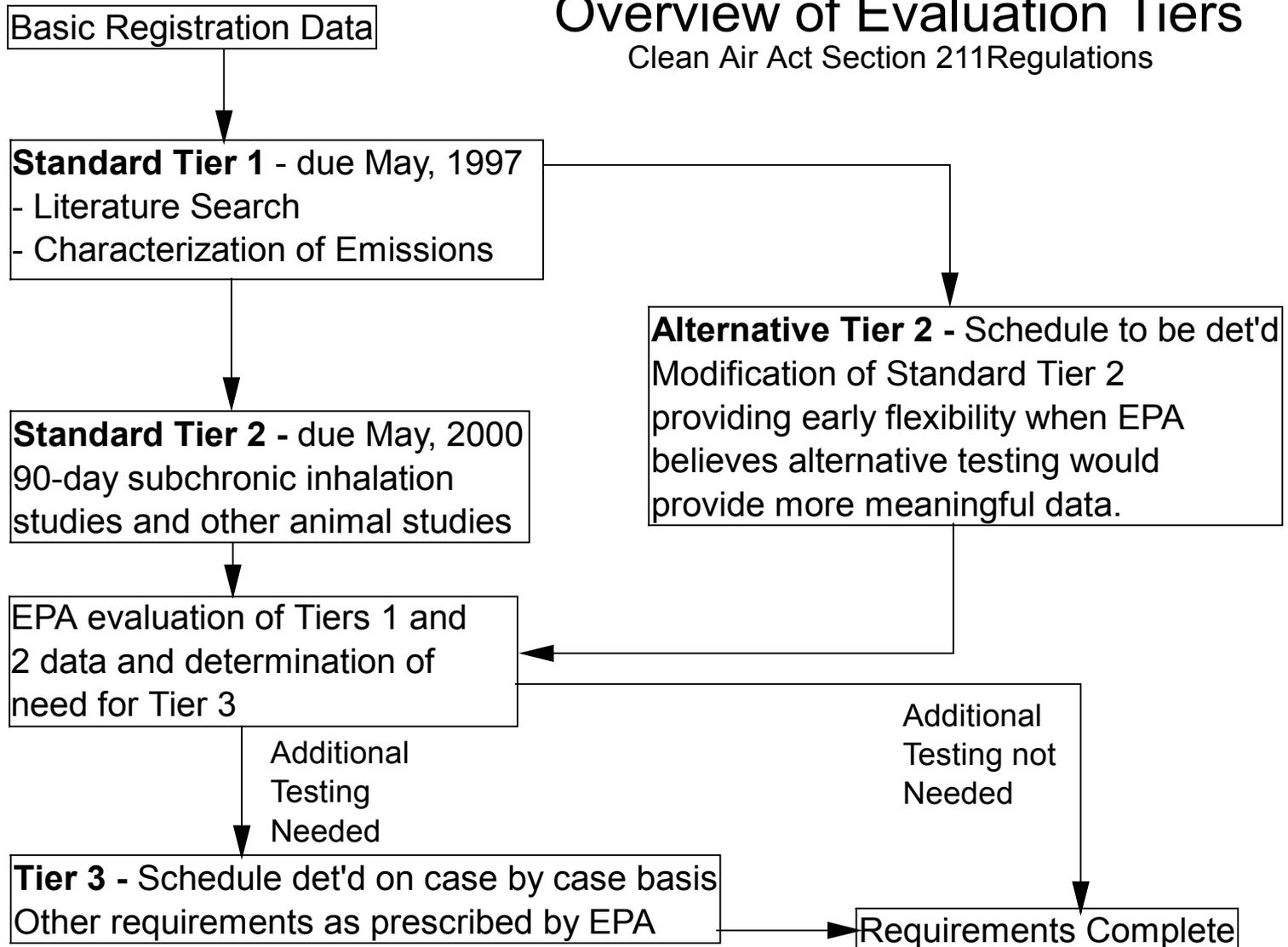
Who does the testing?



- Rule provides for voluntary grouping and cost sharing.
- American Petroleum Institute Consortium for conventional & oxygenated gasolines.
- Biodiesel groups shared cost of testing

Overview of Evaluation Tiers

Clean Air Act Section 211 Regulations



Tier 1 Testing



- Literature search on health/welfare effects of emissions
- Emissions characterization and measurement of hydrocarbon exhaust species such as ketones, aldehydes, alcohols, ethers, PAHs, NPAHs and “atypical emissions” (when applicable)

Tier 2 Toxicology Testing



- Short-term toxicology testing consisting of 90-day subchronic inhalation exposures
- Animals exposed to real-time emissions
- Evaluation of general organ/systemic toxicities
- Endpoints:
 - Carcinogenicity and Mutagenicity
 - Developmental and Fertility Effects
 - Pulmonary Effects
 - Neurotoxic Effects

Alternative Tier 2



- EPA has authority to modify standard toxicology testing (Tier 2)
- In certain cases, a different testing approach may produce more meaningful results.
- e.g., Conventional, Oxy, and MMT Gasolines

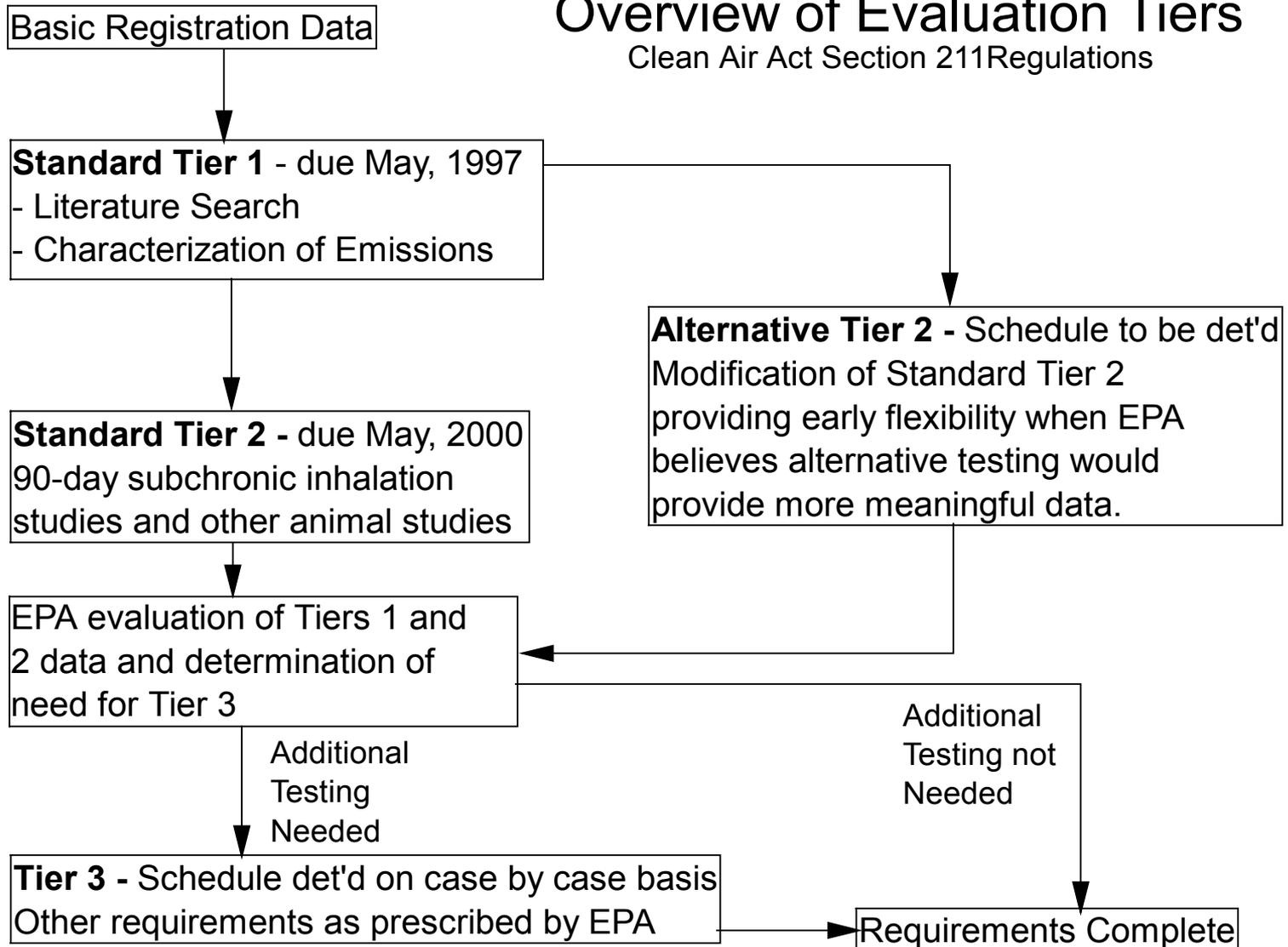
Tier 3 On Case-by-Case Basis



- Targeted to specific concerns
- High degree of discretion based upon previous concerns

Overview of Evaluation Tiers

Clean Air Act Section 211 Regulations



Oxygenate Issues



- Regulations define a separate group for each oxygenate when used at levels above 1 % by weight % oxygen (for diesel)
- e.g., in gasoline separate groups for MTBE, ethanol, TBA, etc.
- E-Diesel, biodiesel, and water emulsions would be considered separate groups.

Health Testing is Advantageous Commercially



- Our experience is that untested fuels can result in public distrust.
- The public is often suspicious of anything new or different in motor fuel.
- All sorts of health problems and performance complaints are attributed to anything new, often without proof.
- A solid testing foundation prior to introduction is in the best interest of successful commercialization.

Diesel Testing Issues



- Can different E-Diesels, different biodiesels, or different water emulsions be grouped for health testing purposes?
 - Are emulsions similar enough that health effects are expected to be the same?
 - Are components different enough to produce emissions with different health effects?

Diesel Testing Issues

- Small Business Exemptions
- Companies under \$50 million total annual sales exempted from testing for non-baseline (oxygenated) fuels
- Companies under \$10 million total annual sales exempted from Tier 2 (but not Tier 1) testing for atypical fuels
- Fuels not meeting ASTM standards are atypical. Flashpoint Issue?

Status of Diesel Testing



- Testing completed for baseline diesel.
- Testing has been submitted for biodiesel. Evaluation of data continues, but so far no unexpected health effects noted.
- Testing for Lubrizol water emulsions (both winter and summer) recently submitted.
- E-Diesel has consulted with EPA on Tier 1 testing. We understand testing is ongoing.

Conclusion



- Emissions speciation and animal exposure health testing provide some assurance that fuels do not result in unexpected toxic effects.
- A solid foundation of health testing can help commercialize a fuel or additive.
- This testing should be a priority for those interested in commercializing Diesel Alternatives

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Questions?