Review of Scientific Literature Regarding the Human Health Effects of Emissions Produced by the Combustion of Ethanol Containing Gasoline and the Effect of Increasing Ethanol Blends on Emissions

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Abbreviations and Technical Terms

API	American Petroleum Institute
Cal/EPA	California Environmental Protection Agency
CARB	California Air Resources Board
CO	Carbon monoxide (a type of air pollutant)
COPD	Chronic obstructive pulmonary disorder
CO_2	Carbon dioxide (a type of air pollutant)
CRC	Coordinating Research Council
CTDEP	Connecticut Department of Environmental Protection
CTDPH	Connecticut Department of Public Health
DEP	Maine Department of Environmental Protection
DEP-BAQ	Maine Department of Environmental Protection, Bureau of Air Quality
DOE	US Department of Energy
E0	Fuel containing no ethanol (also known as conventional fuel)
E5	Fuel containing 5% ethanol
E10	Fuel containing 10% ethanol
E15	Fuel containing 15% ethanol
E20	Fuel containing 20% ethanol
E25	Fuel containing 25% ethanol
E85	Fuel containing 85% ethanol
FASD	Fetal alcohol spectrum disorder
HC	Hydrocarbons (a type of air pollutant)
MECDC	Maine Center for Disease Control
mg/m^3	Milligrams per cubic meter (a concentration of a chemical in air)
MTBE	Methyl tertiary-butyl ether (a fuel oxygenate)
NAAQS	National Ambient Air Quality Standards
NOAEL	No Observed Adverse Effect Level
NO_2	Nitrogen dioxide (a type of air pollutant)
NO_x	Nitrogen oxides (the air pollutants nitrogen dioxide, nitrogen trioxide, and other nitrogen species)
NMHC	Non-methane hydrocarbons (a type of air pollutant)
NMOG	Non-methane organic gases (a type of air pollutant)
NREL	National Renewable Energy Laboratory
OEHHA	California's Office of Environmental Hazards and Health Effects
O_3	Ozone (a type of air pollutant)
PAN	Peroxyacetyl nitrate (a type of air pollutant)
$PM_{2.5}$	Particulate matter less than 2.5 microns in diameter (a type of air pollutant)
ppm	Parts per million (a concentration of a chemical in air or water)
SO_2	Sulfur dioxide (a type of air pollutant)
Subchronic	A medium-term duration of exposure – more than a year, but less than a lifetime
THC	Total hydrocarbons (a type of air pollutant)
USEPA	United States Environmental Protection Agency
VOCs	Volatile organic compounds (a type of air pollutant

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1. Executive Summary

On June 16, 2016, Governor Paul LePage issued an executive order directing the Office of the Maine Center for Disease Control and Prevention (MECDC), in collaboration with the Department of Environmental Protection (DEP), to undertake a review of scientific literature regarding the human health effects of emissions produced by combustion of ethanol-containing fuel, and the effects of increasing ethanol blends on emissions.

The federal Energy Policy Act of 2005 established the National Renewable Fuels Standard, which mandated an increase in the amount of renewable fuels used in gasoline nationally. In 2006, this mandate required a 2.78% renewable fuel content to replace 4.0 billion gallons of conventional fuel, and the requirement was met with ethanol. The 2007 Energy and Security Independence Act expanded the Renewable Fuel Standard program. This expansion required the use of renewable fuels to increase from 9 billion gallons per year in 2008 to 36 billion gallons per year by 2022. Gasoline blended with 10% ethanol (E10) is currently the most commonly used and available ethanol-containing fuel in the U.S., but it is possible that fuel with higher ethanol content will be used to help meet the 2022 goals of the Renewable Fuel Standard program. The US Environmental Protection Agency (USEPA) has already approved the use of fuel containing up to 15% ethanol by volume (E15) for vehicles of model year 2001 and newer, and of fuel containing up to 85% ethanol (E85) in vehicles specifically designed to run on “flex fuels”.

Vehicle emissions have a significant impact on air pollution in more densely populated urban areas and consequently, a significant impact on human health. Studies have indicated that ethanol addition to gasoline can modify vehicle emissions of several pollutants, including: particulate matter, ethanol, acetaldehyde, benzene, 1,3-butadiene, formaldehyde, carbon monoxide, nitrogen dioxide, and sulfur dioxide. Vehicle emissions are increased for some of these pollutants and decreased for others; some of these pollutants contribute to atmospheric formation of other pollutants, such as ozone (O_3) and peroxyacetyl nitrate (PAN). Several of these same pollutants have other non-mobile sources that contribute to ambient air levels, making it challenging to assess the overall health impact relative to conventional gasoline.

MECDC reviewed several studies on the potential impacts of widespread use of ethanol-blended fuel on ambient air quality and health. These were government-initiated studies undertaken by the governments of Canada, Australia, and the state of California. These studies largely relied on models and simulations; specifically, they modelled vehicle emissions, quantified changes in overall emission inventories based on changes in vehicle emissions, quantified atmospheric concentrations of relevant pollutants in ambient air, and conducted health effects assessments of exposure to the estimated concentration of those pollutants in ambient air. In most of these studies, the health impacts of vehicle emissions associated with E10 fuel were evaluated relative to conventional gasoline. All of the studies reached similar conclusions: the widespread use of E10 fuel would either have no substantial effect on predicted public health impacts as compared to conventional fuels, or there would be a net benefit to public health.

There is less information available regarding potential impacts of fuel blended with higher levels of ethanol (e.g., E15, E20, E85). The USEPA, along with several other research groups, have performed studies to measure exhaust emissions from vehicles burning fuel with higher percentages of ethanol. In general, the available studies suggested that increasing the percent of ethanol in blended fuels would increase emissions of hydrocarbons (including ethanol), nitrogen oxides, and particulate matter, while decreasing emissions of carbon monoxide. These models also estimated that increasing ethanol content would increase emissions of acetaldehyde, formaldehyde, and acrolein, but would not cause any substantial change in emissions of benzene or 1,3-butadiene. Both modeling and limited monitoring data indicated that use of very high ethanol blends (e.g., E85, E100) can cause increased levels of atmospheric ozone due to increased vehicle emissions of ozone precursor chemicals (nitrogen oxides, hydrocarbons).

One limitation of health impact analyses completed to date has been a knowledge gap regarding the toxicology of inhaled versus ingested ethanol. The health effects of ingested exposure to ethanol are well known, as ingesting ethanol is a far more common route of exposure than inhaling ethanol vapor. For example, drinking alcohol during pregnancy can cause a number of deleterious effects known as fetal alcohol spectrum disorders. By contrast, the health effects of inhaling ethanol vapor are largely unknown. It is unclear whether inhaling ethanol vapor, alone or when present as a constituent of fuel vapor, can cause health effects that are similar to those caused by oral exposures. To address this question, the USEPA conducted a study in which pregnant laboratory animals were exposed to vapor from 100% ethanol and assessed for developmental health effects in the animals and their offspring. This study was followed by a similar developmental exposure study which assessed the potential health effects of fuel vapor from either fuel with no ethanol, fuel containing 15% ethanol, or fuel containing 85% ethanol. The American Petroleum Institute (API) also commissioned a series of animal studies designed to examine the health effects of vapor from gasoline containing different oxygenates, including ethanol. Overall, there were few effects observed in animals exposed to evaporative emissions from either conventional gasoline or gasoline containing ethanol. The developmental effects observed from inhalation exposure to 100% ethanol vapor during pregnancy were mild, even at very high chamber air concentrations, and were not consistent with those observed for oral exposure to ethanol during pregnancy in animals. Gasoline vapor is a complex mixture of hydrocarbons, and exposure to this vapor itself did cause some observable effects in animal studies. However, the presence of ethanol in gasoline vapor did not clearly exacerbate or otherwise change these effects.

Based on the literature reviewed, there does not appear to be any significant health impacts from the widespread use of E10 gasoline. The potential health impacts of fuel with much higher blends of ethanol (e.g., E20, E85) have been less well studied.

2. Introduction

On June 16, 2016, Governor Paul LePage issued an executive order directing the Office of the Maine Center for Disease Control and Prevention (MECDC), in collaboration with the Department of Environmental Protection (DEP), to undertake a review of the scientific literature regarding the human health effects of emissions produced by the combustion of ethanol-containing fuel, and the effects of increasing ethanol blends on emissions.

Ethanol, the principal type of alcohol found in alcoholic beverages, is produced by fermenting plant sugars. It can be made from corn, sugarcane, and other starchy agricultural products. In the United States, most ethanol is currently made from corn, and the largest use of ethanol is in fuel. Nearly all gasoline distributed in Maine is now blended with 10% ethanol, referred to as E10. A less-common fuel, E85, is a blend of 85% ethanol and 15% gasoline. E10 fuel can be burned in all vehicles manufactured after 1980, whereas E85 fuel can only be burned in specially designed “flex fuel” vehicles.

E10 is available in the Maine market for several different reasons.[1] In 2005, the federal Energy Policy Act established the National Renewable Fuels Standard that mandated an increase in the amount of renewable fuels used in gasoline nationally. In 2006, this mandate required a 2.78% renewable fuel content, to replace 4.0 billion gallons of conventional fuel, and the requirement was met with ethanol. In 2007, the federal Energy Independence and Security Act was passed that required 9 billion gallons of ethanol to be blended into the fuel supply in 2008, increasing to 36 billion gallons of ethanol to be blended into the fuel supply in 2022. There are also federal and Maine tax incentives for the manufacture and distribution of biofuels.[2]

Vehicle emissions have a significant impact on air pollution in more densely populated urban areas, and consequently, a significant impact on human health. Pollutants such as particulate matter with a size of less than 2.5 microns ($PM_{2.5}$), carbon monoxide (CO), nitrogen oxides (NO_x), and hydrocarbons are released when fuel is burned in automobiles and when air/fuel residuals are emitted through the vehicle tailpipe. Gasoline vapors also escape into the atmosphere during refueling and when fuel vaporizes from engines and fuel systems heated by vehicle operation or hot weather. The pollutants in vehicle emissions are known to damage lung tissue, and can lead to and aggravate respiratory diseases, such as asthma; some of the pollutants are associated with excess mortality. Pollutants emitted directly from vehicles are not the only cause for concern. Hydrocarbons can react with NO_x in the atmosphere to create a secondary pollutant, ozone (O_3). Ozone causes coughing, wheezing, and shortness of breath, and can lead to permanent lung damage, making it a significant public health threat.

Studies of ethanol-blended fuels have indicated that ethanol addition to gasoline may modify the vehicle emission and secondary formation of several pollutants, including: particulate matter ($PM_{2.5}$), ethanol, acetaldehyde, benzene, 1,3-butadiene, formaldehyde, carbon monoxide (CO), nitrogen dioxide (NO_2), ozone (O_3), peroxyacetyl nitrate (PAN), and sulfur dioxide (SO_2). The use of ethanol-blended fuels is likely to increase levels of some of these pollutants, and decrease levels of others, making it challenging to assess the overall health impact relative to conventional gasoline.

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[1] See this link for more history: http://www.afdc.energy.gov/fuels/ethanol_blends.html

[2] Maine Public Law 650 provides a state fuel tax incentive of 1 cent per gallon of E10. A federal tax incentive for refiners and distributors exists for certain gasoline blends of ethanol (in the case of E10 the blenders credit is 5.1 ¢ per gallon of ethanol).

As directed by the Executive Order, MECDC has reviewed scientific reports and published peer-reviewed literature about the potential health effects of ethanol-blended fuels. One body of evidence identified and reviewed consists of government-funded studies of the health effects of combustion of ethanol-blended fuels. These studies largely relied on models and simulations; specifically, they modelled vehicle emissions, quantified changes in overall emission inventories based on changes in vehicle emissions, quantified atmospheric concentrations of relevant pollutants in ambient air, and conducted health effects assessments of exposure to the estimated concentration of those pollutants in ambient air. In most of these studies, the health impacts of vehicle emissions associated with E10 fuel were evaluated relative to conventional gasoline.

A second body of literature identified and reviewed consists of scientific studies published in the peer-reviewed literature on controlled animal studies to measure the toxicity of inhaled ethanol, either alone or in combination with other evaporative emissions from gasoline. Ethanol ingestion during pregnancy has been linked to fetal alcohol spectrum disorder (FASD), characterized as craniofacial malformations, persistent developmental and cognitive deficits, and immune system dysfunction in children. The potential hazards of *inhaled* ethanol on the developing nervous system have not been well characterized, and a number of studies have been recently completed to address this knowledge gap.

The Executive Order additionally requested a review of the scientific literature on the effect of increasing ethanol blends on emissions. MECDC identified and reviewed publications regarding use of E85 and other fuel formulations with an ethanol content that is higher than 10% by volume.

This report presents a synopsis of MECDC’s review of these scientific reports and published literature.

3. Review of reports that modeled impacts of ethanol fuel use on ambient air quality and health

MECDC identified several government-funded studies on the potential impacts of widespread use of ethanol-blended fuel on ambient air quality and health. MECDC also identified an additional government report that was primarily a review of the available literature and previously existing reports. There are a number of variables that influence the results of these government reports, which in turn may limit the relevance of their findings to air quality in Maine. These variables include the use of base fuel blends that are different than seasonal fuel blends used in the Northeast, vehicle fleet mixes that may not be representative of Maine, climate differences that may influence evaporative emissions and secondary formation of pollutants, and different emission inventories for non-mobile sources of the same pollutants released by the burning of gasoline. Of the available studies, the one of most relevance to Maine appears to be the 2010 Health Canada study, described below (3A.), which generated model results for a broad eastern region that includes the northeastern U.S.

A. <u>Health Canada Study (2010)</u>

The purpose of the Health Canada (2010) report was to assess the human health implications of a widespread switch from conventional gasoline to E10 fuel. It was conducted in response to the development of Canada's Renewable Fuels Strategy, which will eventually require the increased use of biofuels, including ethanol to reduce the country's greenhouse gas emissions. The health impacts of E10 were compared to a baseline of conventional gasoline.

Human health implications were evaluated through a series of modeling exercises to estimate ambient air concentrations of various pollutants impacted by vehicle emissions, and to then evaluate the resulting health risk associated with these predicted air concentrations. To begin, the report authors modeled the effect of E10 fuel on exhaust emissions of CO, NO_x, $PM_{2.5}$, benzene, 1,3-butadiene, formaldehyde, acetaldehyde and other volatile organic compounds (VOCs) for different vehicle classes, temperatures, and operating conditions. These emission estimates were then applied to a regional emission inventory to estimate changes in the emission inventory based on changes in vehicle emissions. The emission inventories were used in atmospheric models to estimate summer pollutant concentrations at different heights above the ground. The atmospheric models additionally produced estimates of the chemical formation of secondary pollutants (e.g., O_3) from the primary pollutants (e.g., VOCs and NO_x). Personal exposure modeling was performed to estimate daily human exposure to pollutants in several types of microenvironments (e.g., indoor homes, indoor parking garages, in-vehicle, outdoor gas station with refueling in progress). Microenvironment-related exposures were estimated for several age groups (including children) by combining levels of pollutants with time-activity data (i.e., survey data on time spent engaged in activities associated with each microenvironment). Human health risk characterization was performed by linking this microenvironment-level exposure data to established concentration-response functions used to predict impacts of pollutants on health. Non-cancer health outcomes (premature mortality, hospital admission, emergency room visits, acute respiratory symptom days, and bronchitis) were assessed for CO, NO_x, SO_2, $PM_{2.5}$, and O_3 based on concentration-response functions derived from the epidemiological literature. Cancer risks were assessed for those pollutants considered to be cancer-causing (benzene, 1,3-butadiene, formaldehyde, and acetaldehyde) using standard risk assessment methods. These modeling analyses were performed separately for a western region (extending from the western shore of Vancouver Island to the border of British Columbia and Alberta, and covering 500 kilometers on each side of the

US-Canadian border), and an eastern region (covering the most densely populated areas of southeastern Canada in Ontario and Quebec, and most of the northeastern US). The results for the eastern region are of most relevance to Maine, and thus only these results are presented in this report. For the eastern region, emissions were modeled for the year 2000 based on available vehicle registration information, and using model scenarios in which all on-road, gasoline-powered vehicles used either conventional or E10 fuel.

Major findings from the Health Canada Study include:

1) Impact of E10 fuel on vehicle emissions: Model results indicated that, compared to conventional gasoline, use of E10 fuel reduced emissions of CO, VOCs, benzene and 1,3-butadiene, and increased emissions of acetaldehyde and formaldehyde. No changes in emissions of NO_x, $PM_{2.5}$, or SO_2 were found for E10 fuel relative to conventional gasoline.

2) Impact of E10 fuel on air concentrations: Atmospheric modeling indicated that widespread use of E10 fuel had only a minor effect on summertime ambient air concentrations of all pollutants of interest, indicating that the magnitude of changes in emissions were modest, given other non-mobile sources for these pollutants. These changes ranged from an increase of 0.3% (acetaldehyde) to a decrease of 1.3% (benzene).

3) Impact of E10 fuel on human exposure to pollutants: Widespread use of E10 fuel resulted in decreased exposure to benzene and 1,3-butadiene, increased exposure to ethanol and acetaldehyde, and no significant effect on formaldehyde exposure.

4) Human Health Impact: Widespread use of E10 fuel was estimated to result in overall health benefits due to reduced exposure to CO, NO_x, SO_2, $PM_{2\ 5}$, and O_3, though these benefits were small in magnitude. The benefits were mostly due to small reductions in exposure to O_3. Use of E10 fuel was estimated to result in a net decrease in cancer cases, though the magnitude was also small. Ethanol exposure was reported to be well below a California draft health protective concentration of 100 mg/m3.

Report Conclusions:

The overall conclusions of Health Canada in this report were that widespread use of E10 fuel would result in a possible negligible decrease in the number of adverse health effects. In general, there were no substantial differences in predicted health effects between conventional gasoline and E10 fuel scenarios. The report did note that the limited knowledge of health effects associated with inhalation of ethanol itself required that the assessment of this pollutant be more qualitative than the assessments for other pollutants. Health Canada considered the techniques utilized in this assessment to be conservative, and to include the current scientific understanding of vehicle emissions, atmospheric chemistry, human exposure, and human health effects of the studied pollutants.

B. Australia Department of the Environment, Water, Heritage and the Arts Risk Assessment (2008)

The purpose of the Australia Department of the Environment report was to assess the health impacts and costs of use of fuel containing ethanol, as compared to conventional fuel. The report compared the emissions of the light-duty Australian fleet using three different fuel types: conventional fuel, fuel containing 5% ethanol by volume (E5), and fuel containing 10% ethanol by volume (E10). The study covered the major urban areas of Australia: Sydney, Brisbane, Melbourne, and Perth.

The study assessed the emissions, resulting air quality, and subsequent health effects of $PM_{2.5}$, O_3, CO, NO_2, 1,3-butadiene, acetaldehyde, formaldehyde, and benzene. The overall study included several experimental measurement steps and several modeling steps. First, direct measurements were taken of exhaust and evaporative emissions from a small but representative sample of Australia's light-duty on-road vehicle using each fuel type (conventional, E5, or E10). Vehicle emissions data were then combined with fleet inventory data to determine expected total emissions from vehicles. Direct measurements of the formation of O_3 and secondary organic aerosols were also made in a smog chamber for each fuel scenario. Next, air quality models were constructed for two time periods (2006 and 2011) and for the four different fuel use scenarios: 100% of the fleet using conventional fuel; 50% of the fleet using conventional fuel and 50% of the fleet using E10; 100% use of E10; and 100% use of E5. These models combined standard emissions inventories and the emissions measurements described above, for each fuel scenario, in order to estimate population exposure to $PM_{2.5}$, O_3, and NO_2.

Finally, a health impact assessment was completed for the exposure to the air pollutants measured and modeled in previous steps. Exposures to $PM_{2.5}$, CO, O_3, and NO_2 were derived from airshed modelling, while exposures to the remaining air toxins (1,3-butadiene, acetaldehyde, formaldehyde, and benzene) were derived from emission inventories based on experimental measurements. Health effects associated with each air pollutant were identified, and health risks were estimated in terms of the percent relative change in population health incidents resulting from the replacement of conventional fuel with E5 or E10, quantified as the number of people affected annually, as well as the cost increase or savings associated with the health effects. Baseline health impact values for each pollutant were taken from recent official Australian Government Publications, or calculated where recent baselines were not available. Since the use of E5 fuel is not relevant to Maine, findings presented below pertain only to E10 fuel use.

Major findings from the Australia Department of the Environment Study include:

1) Empirical testing of vehicles for emissions showed that for tailpipe (exhaust) emissions, use of E10 fuel reduced levels of $PM_{2.5}$, CO, benzene, and 1,3-butadiene; and increased levels of ethanol, acetaldehyde, and formaldehyde. Results for NO_2 were variable, but overall did not show significant differences by fuel type. For evaporative emissions, addition of ethanol to conventional fuel increases the vapor pressure, and therefore the volatility of the fuel, leading to increased evaporation rates. The E10 fuel was found to be more volatile than conventional fuel, and this resulted in increased evaporative emissions of hydrocarbons (precursors to secondary $PM_{2.5}$ formation), benzene, and ethanol for E10 as compared to conventional fuel.
2) Air quality modeling for criteria pollutants suggested that in general, use of E10 would lead to an increase in population exposure to O_3 and NO_2, and a decrease in population exposures to CO and $PM_{2.5}$.

3) Modeling for air toxics generally showed that use of E10 fuel would lead to increases in formaldehyde and acetaldehyde emissions, small decreases in benzene emissions, and a small decrease in 1,3-butadiene emissions. Changes were all relatively small – less than 2%.
4) Health impacts were summarized by pollutant. Cost savings presented here are in Australian dollars.
    a. For $PM_{2.5}$, each of the E10 fuel use scenarios (50% or 100% of the fleet using E10) resulted in fewer people affected as compared to the conventional fuel scenario, leading to a decrease in health costs of between $19,500,000 and $75,800,000, depending on the year (2006 vs. 2011) and the fuel scenario. Health effects considered included mortality from all causes, respiratory causes, cardiovascular causes, lung cancer, and cardiopulmonary disease; and hospitalizations for asthma, cardiovascular disease, and chronic obstructive pulmonary disease (COPD).
    b. Modeled use of E10 as compared to conventional fuel led to increased modeled O_3 emissions, resulting in an increase in health costs ranging from $130,900 to $579,800. Health effects considered were defined in a previous report by the Australian National Environmental Protection Council, and included mortality, asthma attack, acute respiratory symptoms, restricted work days, minor restricted activity days, and minor symptoms.
    c. For NO_2, both E10 fuel use scenarios resulted in an increase in cases, and a small increase in associated costs of between $370 and $28,400. Health effects considered included acute respiratory symptoms, as well as some portion of the overall health effects of $PM_{2.5}$ and O_3, since NO_2 can contribute to the secondary production of both pollutants.
    d. For CO, current emissions do not produce sufficient pollutant concentrations to cause any health effects, and models suggest that introducing ethanol into fuel will serve to lower emissions even further. Current case counts are negligible, and models suggest they would remain negligible.
    e. Health costs of exposure to 1,3-butadiene and benzene were lower for all E10 fuel scenarios. Health costs of exposure to acetaldehyde and formaldehyde were slightly higher for all E10 fuel scenarios. In total, the study found that the E10 fuel scenarios resulted in a decrease in costs associated with exposure to all air toxics of between $507,000 and $1,216,000. The health effect considered for exposure to these air toxics was mortality.

Report Conclusions:

Taken together, the health savings associated with changes in exposure to the full range of contaminants studied, due to a changeover from conventional to E10 fuel, are significant. For all of urban Australia, in the 2006 model, these cost savings range from approximately $39 million to $77 million; for the 2011 model, cost savings is somewhat lower, due to a more efficient vehicle fleet, at ~ $20- $42 million. In each scenario, the majority of the cost savings was due to avoidance of $PM_{2\ 5}$ exposure and associated mortality.

In summary, this study found a health benefit to the urban Australian population from a projected changeover from conventional fuel to E10 fuel. Although sensitivity analyses showed significant variability in these estimates, the conclusions are quite robust to parameter specification, and show a consistent health benefit.

C. California Office of Environmental Health Hazard Assessment (OEHHA) Risk Assessment (1999)

The purpose of the California OEHHA report (1999) was to assess the public health implications of the use of ethanol as an oxygenate in gasoline, as compared to the use of gasoline with no additive oxygenate, and to the use of gasoline with the oxygenate methyl tertiary-butyl ether (MTBE). It was commissioned as part of California's decision to phase out the use of MTBE, given the health and environmental risks associated with that chemical. The health impacts of two ethanol-containing fuels, one containing 10% ethanol by volume (E10) and one containing 5.7% ethanol by volume, were compared to the health impacts of conventional fuel and to the health impacts of fuel containing MTBE.

As with the other studies described here, OEHHA evaluated potential risks to human health through a series of models that estimated emissions, ambient air concentrations, exposures, and health outcomes from each of the fuel types studied. The first two steps, estimating the changes first in emissions and then in ambient air concentrations of pollutants that would result from a switch to ethanol-containing fuels, were conducted by the California Air Resources Board (CARB) and are described in a separate study (CARB 1999). These models estimated the effect of all mobile source emissions, including tailpipe emissions from all on-road vehicles, and evaporative emissions from stationary and running cars, fueling, and fuel spillage, on levels of the air pollutants ethanol, 1,3-butadiene, formaldehyde, acetaldehyde, CO, benzene, hexane, toluene, peroxyacetyl nitrate (PAN), $PM_{2.5}$, NO_2, and O_3. A separate set of models was used to estimate the atmospheric transformation of primary pollutants like VOCs into secondary pollutants like O_3, and to incorporate these changes in levels of primary and secondary pollutants into the overall estimates of ambient air concentrations. These models were all constructed around the South Coast airshed, a well-studied area of the state that is highly affected by air pollution, and were used to estimate ambient air concentrations for 2003. The model was calibrated by comparing measured data from 1997 to modeled predictions for the same year.

Health impacts of concern were estimated by combining these ambient levels with existing "health assessment values," numbers that describe the dose-response relationship for each pollutant and health effect, currently available from the California Environmental Protection Agency (Cal/EPA) or the USEPA. In the case of a few contaminants with no health assessment values available, OEHHA used proposed values developed by other California regulatory programs, or calculated their own "health protective concentrations" for the purpose of the report. Health risks were quantified for each pollutant, and then cumulative risks were estimated by combining the individual risk levels derived from each individual pollutant. Specific health outcomes were separated into cancer and non-cancer endpoints; some pollutants were assessed for both types of health endpoint. Cancer effects considered were the number of lifetime cancer cases associated with each exposure, and non-cancer effects considered were eye, skin, and respiratory irritation and inflammation, reduced birthweight in infants, and hematotoxicity (toxicity to blood cells).

Major findings from the California OEHHA Study include:

1) Impact of ethanol-containing fuels on overall exposures: Compared to the non-oxygenated fuel scenario, CARB and OEHHA models predicted use of ethanol-containing fuels would result in small increases in exposure to acetaldehyde, benzene, formaldehyde, and PAN, and larger increases in exposure to ethanol; moderate decreases in exposure to CO; and no changes in predicted exposures to 1,3-butadiene, NO_2, O_3, or $PM_{2.5}$.

2) Human health impact of ethanol-containing fuels: Cumulative cancer and non-cancer risks were considered separately. The models showed a significant drop in cumulative expected cancer cases from 1997 to 2003, due to improved vehicle efficiency and decreased overall emissions, regardless of fuel type. Upper bound cumulative cancer risks derived from the 2003 model suggested that the use of E10 fuel would cause 187 excess cancer cases as compared to 181 for conventional fuel, mostly due to increased benzene emissions. This difference was viewed as much smaller than the uncertainty in the estimates themselves, and so was deemed negligible by the report authors. Estimates of cumulative non-cancer risk suggested that the use of ethanol-containing fuel, as compared to conventional fuel, would result in small increases in the number of cases of acute eye irritation and chronic respiratory irritation; and a small decrease in the number of cases of acute respiratory irritation.

Report Conclusions:

California OEHHA concluded that there were no substantial differences in the predicted public health impacts of combustion of E10 as compared to conventional fuel, and that any differences found were too small to justify recommending any one fuel over another. In general, these models identified significant improvements in emissions and health effects for all fuel types when comparing the year 1997 to the year 2003, which were the result of a newer and more efficient vehicle fleet in 2003.

D. Connecticut Departments of Environmental Protection and Public Health Study (2006)

In 2006, the Connecticut General Assembly enacted legislation directing the Departments of Environmental Protection (CTDEP) and Public Health (CTDPH) to examine the public health implications of exposure to ethanol and hazardous air pollutants unique to ethanol-blended fuel, the effects of ethanol fuel use on motor vehicle emissions, and the health risks associated with long-term exposure to ethanol or ethanol-blended gasoline.

The CTDEP/DPH study largely consisted of a review of literature and studies showing correlations between vehicle emissions of pollutants and the differences in fuel blends that have been formulated to stabilize volatility under different climate conditions. The 1999 California OEHHA and CARB studies described above were extensively reviewed and discussed. The literature review was supplemented with an examination of available ambient air monitoring data that allowed for a comparison of air quality before and after the introduction of ethanol-blended fuel.

Major findings from the CTDEP/DPH study include:

1) The use of ethanol in gasoline does not cause the release of any new air toxics, but rather increases or decreases the levels of contaminants present in ambient air. The change in ambient concentrations is expected to be modest.
2) The use of E10 fuel is expected in increase NO_2 emissions as compared to conventional gasoline, which may impact O_3 production.
3) Ethanol may increase evaporative emissions by enhancing the permeation of fuel through intact hoses, seals, and - if it is not metal - the gas tank itself. However, the contribution of permeation to the overall

emission rate for VOCs from gas tanks and engine vehicles was not well understood at the time the CTDEP/DPH study was completed.

4) Specific changes in atmospheric levels of air pollutants resulting from the widespread use of ethanol-blended fuel could not be quantified or estimated for Connecticut, because most of the reviewed data were from studies in California. CTDEP/DPH believed these data could not be reliably extrapolated to the northeast US due to differences in fuel blends, climate, and vehicle fleet mix.
5) The expected increase in atmospheric air levels of ethanol predicted by the CARB/CalEPA study (5.1 parts per billion expected to increase to 8.8 parts per billion) was viewed as consistent with measured air levels in Porto Allegre, Brazil, where 17% of vehicles run on 100% ethanol fuel and average ambient air ethanol levels were 12 parts per billion.
6) CTDPH did not view these estimated air levels of ethanol to be a health concern. They estimated that the inhaled dose of ethanol at the level predicted by CARB/CalEPA was 40,000 times less than one alcoholic drink per day and 2,000 times less than the dose from an eight-ounce glass of orange juice.
7) As other studies have indicated, vehicle exhaust emissions of the chemical acetaldehyde were expected to increase with burning of ethanol-blended fuel. CTDEP examined measurements of acetaldehyde from a monitoring station in East Hartford before and after the widespread switch from fuel blended with the oxygenate MTBE to fuel blended with ethanol. Average summertime acetaldehyde levels were 1.15 parts per billion in 2003, the summer before the conversion to ethanol-blended fuel, and 1.43 parts per billion (25% higher) the summer of 2005 after conversion. This is consistent with modeled results from California suggesting only a small increase in ambient air levels. It was also noted to be consistent with monitoring data from Denver, Colorado, that could not detect any increase in acetaldehyde as a result of the switch to ethanol-blended fuel. The measured concentration of 1.43 parts per billion was below the Connecticut minimum exposure level for cancer risk concerns and thus not a significant contributor to cancer risk.
8) The ultimate effect of ethanol-blended fuels on summertime O_3 levels in Connecticut was viewed as uncertain, but monitoring data did not indicate any increase associated with the switch in fuels.

Report Conclusions:

Despite noting that data of direct relevance to Connecticut were not available, the report authors stated that the available data does not suggest that ethanol blended fuel will significantly degrade air quality or lead to public health risk. This conclusion was based in part on the recognition that there are numerous background sources of fuel-related emissions, so that modest changes in emissions associated with widespread use of ethanol-blended gasoline can be expected to have an overall minor impact on air quality.

4. Review of scientific literature on the effect of increasing ethanol blends on vehicle emissions

To understand the health risks of ethanol fuels in the context of their increasing presence, it is important to understand whether increasing the percentage of ethanol in gasoline dramatically alters vehicle emissions. To help answer this question, the USEPA, along with several other research groups, performed studies measuring exhaust emissions from vehicles running on gasoline with higher percentages of ethanol. These emission measurement studies focus on directly quantifying levels of various compounds in exhaust emissions from vehicles run on conventional fuel, E10, E15, and E20 gasoline in a controlled laboratory environment. Additionally, several other research groups have focused on modeling and measuring changes in overall ambient air quality with the use of increasing ethanol content in gasoline and how those changes may adversely impact human health.

Exhaust emissions from intermediate ethanol gasoline blends

Gasoline blended with ethanol at a percent volume greater than 10%, such as E15 or E20, is often referred to as intermediate ethanol blended-gasoline. The Coordinating Research Council (CRC)[3] conducted a study to measure exhaust emissions from 15 different vehicles running on intermediate ethanol blends (CRC 2009). Vehicles from model year 1994 through 2006 were selected to represent the most common vehicles on the road based on high sales volumes, and all vehicles tested complied with Federal vehicle emission standards. Exhaust emissions, including CO, total hydrocarbons (THC), non-methane hydrocarbons (NMHC), NO_x, and carbon dioxide (CO_2) were measured under controlled laboratory conditions with vehicles burning conventional fuel, E10 or E20 gasoline. As compared to conventional fuel, vehicles burning E10 and E20 produced less CO and hydrocarbon emissions, while increasing NO_x exhaust emissions (CRC 2009). The reduction in CO emissions was similar for both E10 and E20 gasolines.

The National Renewable Energy Laboratory (NREL), part of the U.S. Department of Energy (DOE), measured exhaust emissions from vehicles run on conventional fuel, E10, E15, and E20 (NREL 2009). The 16 vehicles selected for this study ranged from model year 1999 to 2007. There were no significant changes in NO_x or non-methane organic gases (NMOG) levels in exhaust emissions with the use of E10, E15, or E20. CO and NMHC levels were significantly reduced with E10, E15, and E20 fuels as compared to levels from conventional fuel. The CO and NMHC reductions were similar between the three intermediate ethanol blended fuels. The presence of ethanol increased the levels of ethanol, acetaldehyde, and formaldehyde levels in the vehicle exhaust emissions.

The USEPA in collaboration with the DOE and the CRC conducted an extensive study designed to better understand the effects of altering different fuel properties, including ethanol content, on the release of both regulated and unregulated vehicle exhaust emissions (USEPA 2013a and USEPA 2013b). In this study, the USEPA selected 15 2008 model year vehicles and examined how changes in the different parameters of fuel, including

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[3] *"The Coordinating Research Council (CRC) is a non-profit organization that directs, through committee action, engineering and environmental studies on the interaction between automotive/other mobility equipment and petroleum products. The Sustaining Members of CRC are the American Petroleum Institute (API) and a group of automobile manufacturer members (Chrysler, Daimler, Ford, General Motors, Honda, Mitsubishi, Nissan, Toyota, and Volkswagen). CRC research programs are managed by five technical committees (Advanced/Vehicle/Fuel/Lubricants, Atmospheric Impacts, Emissions, Performance, and Aviation.)"* (https://crcao.org/about/index.html)

ethanol content (none, E10, E15, and E20), aromatic content, vapor pressure, and distillation properties affected CO, THC, methane, NMHC, NO_x, and $PM_{2.5}$ exhaust emissions (USEPA 2013a and USEPA 2013b). A subset of specific compounds, including acetaldehyde, formaldehyde, acrolein, benzene and 1,3-butadiene, was also evaluated. The 15 vehicles were run under specific conditions using each type of gasoline. Pollutant levels were then measured in the collected exhaust emissions. Using the measurement data, the USEPA developed a model to account for changes in the multiple parameters tested. When all other parameters were taken into account, the model predicted that increasing ethanol blends would generally increase hydrocarbons (THC, NMOG, NMHC and methane), NO_x, and $PM_{2.5}$ emissions, while decreasing CO emissions. The model also estimated increases in acetaldehyde, formaldehyde, and acrolein with increasing ethanol blends. Increasing ethanol content in gasoline was not associated with any change in benzene or 1,3-butadiene emissions.

The NERL/DOE study also measured CO, HC and NO_x exhaust emissions from small non-road engines, such as generators, leaf blowers, line trimmers, and power washers run with conventional fuel (E0), E10, E15, and E20 gasoline (NREL 2009). In small non-road engines, relative to conventional fuel, CO emissions with E10, E15, and E20 were decreased. Hydrocarbon levels were also reduced with most engines running on E10, E15 or E20. NOx levels were increased with use of E10, E15, or E20 gasoline in the small engines as compared to E0 levels.

From the available studies and reviews conducted by the USEPA and CRC, increasing the ethanol content of gasoline up to 20% has the general effect of decreasing CO and increasing ethanol, acetaldehyde and formaldehyde emissions. The results are mixed for impacts on NO_x, HC (THC, NMOG, NMHC), and particulate matter emissions, and may depend on vehicle model year (CRC 2008; Hochhauser and Schleyer 2014; Karavalakis et al. 2012; USEPA 2013a; USEPA 2013b).

Air modeling and health effects studies

Utilizing a computer model that takes into account various atmospheric changes in order to model overall ambient air quality, a researcher at Stanford University evaluated how switching to E85 fuel could impact air quality and human health (Jacobson 2007). Model simulations were run to estimate the change in emission profiles between gasoline only use and a wholesale switch to E85 gasoline use in the year 2020. Model simulations were run for the Los Angeles area and the US as a whole. For both Los Angeles and the US, the use of E85 gasoline increased ethanol, acetaldehyde, and formaldehyde air levels, while decreasing benzene and 1,3-butadiene levels. The model predicted increased O_3 levels in the Los Angeles area and Northeast, but slightly decreased levels in the Southeast. Using the model-predicted levels of acetaldehyde, formaldehyde, benzene, and 1,3-benzadiene estimates of the number of cancer cases resulting from exposure to these chemicals were calculated. There was little difference between the number of cancer cases from changes in acetaldehyde, formaldehyde, benzene, or 1,3-benzadiene levels with use of gasoline only versus E85 gasoline use in the year 2020. However, there were increases in mortality rates, hospitalizations, and asthma-related emergency room visits due to the increased atmospheric O_3 levels with the use of E85 gasoline over baseline levels from gasoline only. Overall, the author concludes “In sum, due to its similar cancer risk but enhanced O_3health risk in the base emission case, a future fleet of E85 may cause a greater health risk than gasoline. However, because of the uncertainty in future emission regulations, E85 can only be concluded with confidence to cause at least as much damage as future gasoline vehicles. Because both gasoline and E85 emission controls are likely to improve, it is unclear whether one could provide significantly more emission reduction than the other.” (Jacobson 2007).

There are atmospheric monitoring data that supports the modeling results from Jacobson (2007) indicating higher ethanol blends may increase O_3 levels. In Brazil, consumers have a choice of using E20 or E25 gasoline or E100, that is, 100% ethanol fuel, in their flex-fuel vehicles. Two research groups have taken advantage of this unique fuel use situation in São Paulo, Brazil to measure and model ozone levels resulting from changes in the populations fueling habits (Salvo and Geiger 2014, and Scovronick et al. 2016).

In the years between 2009 and 2011 market forces caused the use of E20/E25 gasoline versus E100 gasoline to vary dramatically in São Paulo, Brazil. In the study by Salvo and Geiger, air monitoring data for ozone, NO_x and CO in São Paulo, Brazil was analyzed along with a host of metrological factors and traffic conditions that can influence air quality for this same time period. Using empirical air pollution data and accounting for various metrological and road traffic conditions, when E20/E25 use increased from 14 to 76% usage, O_3 levels in São Paulo decreased by approximately 20% (Salvo and Geiger 2014). While O_3 levels decreased with this change in fuel use, NO_x and CO increased with the increased use of E20/E25 fuels. Overall, the study authors conclude "Our present study has shown that under atmospheric conditions observed in São Paulo, concentrations of two air pollutants, specifically NO_x and CO, may increase whereas that of O_3 falls on raising the gasoline fuel share. We caution that the concentration of particles, specifically fine particulate matter, may also increase under that situation." (Salvo and Geiger 2014).

Scovronick and colleagues modeled ozone and $PM_{2.5}$ levels for the projected use of ethanol-based fuels or with projected fuel demand met with gasoline only in São Paulo, Brazil. The modeling effort took into account emission sources from vehicle exhaust and from agricultural practices such as burning sugarcane during harvests and slash-and-burn deforestation unrelated to sugarcane (Scovronick et al. 2016). The projected agricultural emission sources were similar between the two fuel use scenarios (Scovronick et al. 2016). In the ethanol-based fuel use scenario, O_3 and $PM_{2.5}$ levels were increased relative to the gasoline only scenario. These increases in ozone and $PM_{2\ 5}$ equated to the population in São Paulo living an estimated 1,100 additional life years in the first year of a gasoline only scenario compared to a business as usual ethanol fuel scenario. Based the modeling results the researchers conclude "Our findings suggest that, contrary to what is often claimed, a transport fuel policy in São Paulo State that prioritizes gasoline over ethanol could result in lower $PM_{2.5}$ and ozone and less premature mortality from air pollution. Specifically, the expansion of ethanol production and use, in line with government projections, could lead to tens of thousands fewer life-years lived per year compared to a fossil fuel scenario. However, we stress that this is not an argument in favor of fossil fuels, but instead demonstrates the need to continue to limit emissions in the transport sector, with strategies likely to include a combination of improved vehicle technologies, economic incentives and modal shifts towards mass transit and active travel." (Scovronick et al. 2016).

5. Evaluation of Maine air pollution monitoring data before and after the introduction of E10 Fuel

The Maine Department of Environmental Protection – Bureau of Air Quality (DEP-BAQ) operates and maintains a statewide ambient air quality monitoring network for a variety of air pollutants. Some monitoring sites in the network (e.g., Portland Deering Oaks Park and Portland Tukey's Bridge) are particularly well suited to characterize and be representative of mobile source emissions in an area, since that was an intentional and important consideration in choosing the site locations.

Table 1 below provides a listing of air pollutants potentially impacted by vehicle emissions along with those pollutants for which Maine's air quality monitoring network has data available.

Table 1:

Gasoline Vehicle Emission Pollutants Identified in Studies Reviewed in this Report	Measured at a Site in Maine's Air Quality Monitoring Network?
Particulate Matter 2.5 microns and smaller ($PM_{2.5}$)	Yes
Carbon Monoxide (CO)	Yes
Nitrogen Dioxide (NO_2)	Yes
Sulfur Dioxide (SO_2)	Yes
Ozone (O_3)	Yes
Ethanol	No
Formaldehyde	No
Acetaldehyde	No
Benzene	Yes
1,3-butadiene	Yes
Peroxyacetyl Nitrate (PAN)	No

The DEP-BAQ examined Maine monitoring data for any obvious changes in air pollution levels before and after the introduction of E10 fuel in Maine, which started around June 2008. As the majority of the DEP's monitoring activity is focused on satisfying federal and state requirements to demonstrate ongoing compliance with the National Ambient Air Quality Standards (NAAQSs), the usual data compilations to support compliance monitoring are not ideally suited for evaluating changes in air quality due relative to changes in fuel blends. NAAQS pollutants have different averaging times (1-hour, 3-hour, 8-hour, 24-hour, annual). These averaging times are then tracked for compliance purposes in different ways. For example, the NAAQS standard for NO_2 is tracked as the 98th percentile of 1-hour daily maximum concentrations, averaged over 3 years. O_3 is tracked as the annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years. $PM_{2.5}$ is tracked as the annual mean, averaged over 3-years. Nonetheless, these air quality data are computed in a consistent way over time for any given pollutant, and thus can be evaluated for any obvious trends before and after E10 gasoline began entering Maine's distribution supply.

DEP-BAQ staff report the overall long-term trends of $PM_{2\ 5}$ concentrations have been declining for both the 24-hour and annual averaging times used to measure compliance with the NAAQS. Trends in CO levels (using the metric of 2^{nd} highest 8-hour or 1-hour averages) have either been declining or have shown no change. Trends in NO_2 levels (using the metric of the maximum 1-hour average) show a slight decline in both the northern and southern Maine monitoring locations, while the Portland site showed a slight increase during the past few years.

Even so, air quality for NO_2 at the Portland site is still better statewide after the introduction of E10 gasoline in 2008 than it was before. Trends in SO_2 levels (using the NAAQS metric of the 99th percentile maximum 1-hour average) show a decline at all of the Maine monitoring locations, which have either continued after the introduction of E10 gasoline in 2008, or most recently have remained relatively stable. Trends in O_3 levels (using the NAAQS metric of the fourth highest 8-hour average, averaged over three years) show a decline at all of the Maine monitoring locations, which have either continued after the introduction of E10 gasoline in 2008 or most recently have remained relatively stable. Trends in benzene levels (using the metric of an annual average of 24-hour samples collected every 6-days) covering the time-period before and after the introduction of E10 fuel in Maine are available only for a sampling site in Rumford and one in Lewiston. Both locations show trends of decreasing benzene levels.

In conclusion, none of the available Maine air monitoring data for pollutants associated with vehicle exhaust emissions show any clear evidence of increasing since the introduction of E10 gasoline in 2008. However, Maine does not have monitoring data for ethanol or acetaldehyde, the chemicals mostly likely to increase in ambient air due to widespread use of ethanol-blended fuel.

6. Studies of health effects on laboratory animals exposed by inhalation to ethanol and ethanol fuel evaporative emissions

Health impact analyses completed to date have been limited by a knowledge gap regarding the toxicology of inhaled versus ingested ethanol. The health effects following oral ethanol exposures are well known, as ingesting ethanol is a far more common route of exposure than inhaling ethanol vapor. For example, drinking alcohol during pregnancy can cause a number of toxic effects known as fetal alcohol spectrum disorders. These disorders can range in severity from abnormal facial development, growth retardation, and severe learning disabilities to more subtle changes in behavior and difficulty learning in the infant and child as they develop. In comparison, the health effects of inhaling ethanol are largely unknown. It is unclear whether inhaling ethanol vapor, alone or when present as a constituent of gasoline vapor, can cause similar health effects as oral exposures.

Very few studies in humans have been conducted to address this knowledge gap. One group of researchers evaluated exposure to ethanol vapor in healthy adult volunteers to help better understand the potential health effects of adding ethanol to gasoline (Nadeau et al. 2003 and Tardiff et al. 2004). However, these evaluations in humans were not comprehensive toxicological studies, and did not address ethanol exposures in potentially the most sensitive human population, pregnant women and the developing fetus.

As there are multiple ethical issues involved in exposing humans, especially the developing fetus, to ethanol in controlled inhalation studies, researchers have turned to conducting studies in animals to help address this gap in knowledge. In animal studies, researches can strictly control the multiple aspects of a chemical exposure, including the route of exposure, the length of exposure, how much the animal is exposed to, and at what life stage the exposure occurs. Animal studies also offer the advantage of testing multiple health outcomes in a single study, and post-mortem dissection and examination of various organs that may be adversely impacted by the chemical exposure. To model inhalation exposures to gasoline evaporative emissions, researchers utilize inhalation chambers in which test animals, typically rats or mice, are exposed to a vapor by replacing the ambient air in the chamber with a specific concentration of vapor for varying amounts of time. Using inhalation chambers, researchers have conducted several studies to assess the potential health effects of exposure to ethanol vapor, and vapor from gasoline with or without ethanol.

To address the question of whether inhaling ethanol can cause similar health effects as ingesting ethanol during pregnancy, the United States Environmental Protection Agency (USEPA) conducted a developmental inhalation exposure study using vapor from 100% ethanol (Beasley et al. 2014; Boyes et al. 2014; Oshiro et al. 2014). The USEPA followed this study with a similar developmental exposure study to assess the potential health effects of gasoline vapor from either gasoline with no ethanol, or E15 or E85 ethanol blends (Bushnell et al. 2015; Herr et al. 2016; Oshiro et al. 2016). In addition to these two developmental studies, the American Petroleum Institute (API) commissioned a series of studies designed to examine the health effects of vapor from gasoline containing different oxygenates, including ethanol. The API studies include a developmental study, a reproductive study, and a short term subchronic study (Clark et al. 2014; Gray et al. 2014 O’Callaghan et al. 2014; Roberts et al. 2014; Schreiner et al. 2014; White et al. 2014). An additional research group performed a short term inhalation exposure study in rats to gasoline vapor containing ethanol to better understand the effects of inhalation exposures to ethanol-blended gasoline evaporative emissions (Chu et al. 2005).

A. Human exposures studies

A research group from the University of Montreal performed an ethanol exposure study with adult volunteers to help address concerns of potential adverse health effects from involuntary exposure to ethanol vapor with the use of gasoline containing ethanol (Nadeau et al. 2003). In this study, five healthy adult male volunteers were exposed to ethanol vapor in large exposure chambers. Ethanol vapor concentrations in the inhalation chamber air were 0 (control group), 250, 500, and 1,000 ppm. The volunteers were exposed for 6 hours per day on five different days separated by at least 24 hours (Nadeau et al. 2003). Following the exposures, ethanol concentrations were measured in the blood, and a series of neurological tests were administered before and after each ethanol vapor exposure.

Ethanol concentrations in the blood were only detectable following exposure to the highest ethanol vapor concentration of 1,000 ppm. The ethanol blood concentrations were approximately 100 to 300 times lower than ethanol blood concentrations associated with mild intoxication (Nadeau et al. 2003). In the neurological tests designed to assess motor function, no significant changes were following exposure to 1,000 ppm ethanol vapor. Based on these results the researchers conclude “this study suggests that acute exposure to ethanol at 1,000 ppm or lower or to concentrations that could be encountered upon refueling is not likely to cause any significant neuromotor alterations in healthy males” (Nadeau et al. 2003).

B. USEPA Studies

1. USEPA 100% ethanol developmental study

In this study pregnant rats were exposed to 0 (clean air control), 5,000, 10,000, or 21,000 ppm ethanol concentrations in inhalation chambers for 6.5 hours per day for 12 days. These concentrations, particularly the 21,000 ppm concentration, were selected to produce blood ethanol concentrations in the pregnant rats similar to blood ethanol concentrations from oral ethanol exposures during pregnancy that are associated with adverse health effects in offspring (Beasley et al. 2014). These 5,000, 10,000, and 21,000 ppm ethanol vapor concentrations are approximately 50,000 to 200,000 times greater than ethanol vapor concentrations measured at fueling stations, which are typically less than 0.1 ppm (Oshiro et al. 2014 and Zielinska et al. 2012). Following exposure, the pregnant rats were allowed to give birth, and the offspring were subjected to a series of tests to evaluate their neurological function, general physiology, and immune responses.

Overall, neurological function, general physiology, and immune response test results were largely normal in offspring exposed to ethanol during pregnancy. While there were some significant differences in several individual tests between the ethanol exposure groups and control group, the authors suggest that these small differences are not likely to be of biological significance. These researchers also noted that while some changes in learning and memory were seen in offspring exposed to the highest concentration of ethanol, there was an overall lack of effect on cognitive responses as compared to the severity of cognitive defects observed following oral ethanol exposure during pregnancy (Oshiro et al. 2014). The authors postulated the overall lack of effect is likely due to the way ethanol is broken down in the body following oral exposure as compared to inhalation exposure (Oshiro et al. 2014).

2. USEPA E0, E15, E85 developmental study

In inhalation chambers, separate groups of pregnant rats were exposed to 3,000, 6,000, and 9,000 ppm air concentrations of gasoline vapor isolated from gasoline with no ethanol (E0), E15, or E85. These gasoline air vapor concentrations do not represent typical human exposures either in ambient air or in environments with elevated evaporative emission levels, such as fueling stations or enclosed garages (Bushnell et al. 2015). These 3,000, 6,000, and 9,000 ppm gasoline vapor concentrations are approximately 4000 to 800,000 times greater than vapor levels that a typical person might encounter. The actual ethanol vapor concentrations in the inhalation chamber air with the E15 and E85 fuel are approximately 6,000 to 50,000 times higher than ethanol concentrations measured at fueling stations (Zielinska et al. 2012). As the study authors note the gasoline vapor concentrations were selected to more clearly examine the concentration-effect relationship between exposure and any adverse developmental endpoints (Bushnell et al. 2015). Similar to the 100% ethanol study, exposures took place for 6.5 hours per day for 12 days, and following birth the offspring were subjected to a series of tests of neurological function, general physiology, and immune response.

There were no striking effects observed in any of the neurological, physiological or immunological parameters tested in the offspring. Based on the results from multiple neurological screening tests the authors conclude that the ethanol content of the gasoline vapors "did not systematically alter the outcomes of the assessments" (Bushnell et al. 2015). Several tests of sensory function displayed some statistical significance between the E0, E15 and E85 exposure groups, but the changes were not dependent on the presence of ethanol in the gasoline vapor, and were more likely false positives rather than true changes in sensory function (Herr et al. 2016). Comparing the cognitive function test results from exposure to 100% ethanol to the results of this developmental exposure study the authors suggest that "Similar effects were not consistently observed in a previous study of inhaled ethanol, and thus these effects cannot be attributed to the concentration of ethanol in the mixture" (Oshiro et al. 2015).

C. API Studies

1. API developmental study

The API developmental study was designed to assess whether exposure during pregnancy to evaporative emissions from gasoline with no ethanol or gasoline with ethanol causes any developmental alterations in rats. In this study pregnant rats were exposed to clean air only or 2,000, 10,000 or 20,000 mg/m^3 concentrations of gasoline vapor from either baseline gasoline containing no ethanol or E10 gasoline[4]. The gasoline vapor concentrations selected for the API studies are more than 20,000 to 200,000 times greater than typical gasoline vapor concentrations present when refueling a vehicle (Roberts et al. 2014). Under a worst case exposure scenario at a fueling station, the gasoline vapor concentrations used in the API studies are still approximately 300 to 3,000 times greater than an extreme real word exposures (Roberts et al. 2014). The ethanol vapor level in the total E10 gasoline at the 2,000, 10,000 or 20,000 mg/m^3 concentrations is approximately 1,000 to 10,000

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[4] The API studies reported gasoline vapor concentrations in mg/m^3. For comparison, the baseline gasoline vapor concentrations of 2,000, 10,000 and 20,000 mg/m^3 are approximately equal to 663, 3,314 and 6,629 ppm. E10 gasoline vapor concentrations of 2,000, 10,000 and 20,000 mg/m^3 are approximately equal to 742, 3,712 and 7,423 ppm. (Conversions calculated assuming a standard temperature of 25°C and atmospheric pressure at 760 mmHg, and using average molecular weights for the gasoline vapors as presented in Henley et al. 2014).

times greater than ethanol levels measured at service stations (Zielinska et al. 2012). Exposures were carried out in inhalation chambers for 6 hours per day. The researchers also suggest that the exposure time of 6 hours per day far exceeds the typical time a person would be exposed to gasoline vapor while refueling a vehicle (Roberts et al. 2014). The exposures started on day 5 of the pregnancy and ran through day 20, for a total of 15 days of consecutive exposure. On day 21 the pregnant females were euthanized and the dams and fetuses examined.

The only effect noted in the pregnant rats was a slight, but statistically significant decrease in body weight in the group exposed to the highest concentration, 20,000 mg/m^3, of E10 gasoline vapor as compared to the clear air exposed group (Roberts et al. 2014). This decrease was attributed to a slight reduction in food consumption during the exposure period. Exposure to vapor from gasoline only or E10 gasoline had no discernable effect on a number of developmental endpoints examined. The researchers did find an increase in skeletal variations in fetuses from dams exposed to 10,000 mg/m^3 E10 gasoline vapor. However, they suggest that this finding was likely spurious as it was not observed in the 2,000 or 20,000 mg/m^3 E10 exposure groups (Roberts et al. 2014). Based on these results and those for other oxygenated fuels, the authors conclude "Indeed the minimal effects to the general health of the adult animals and fewer effects to prenatal development suggest that evaporative emissions of gasoline and gasoline/oxygenate blends are not selective developmental toxicants and pose minimal risk to human prenatal development" (Roberts et al. 2014).

2. API reproductive study

A one generation reproductive study was conducted to examine whether exposure to baseline gasoline or E10 gasoline vapor can alter the reproductive capacity of rats. In this study both male and female rats were exposed to clean air only or 2,000, 10,000 or 20,000 mg/m^3 baseline gasoline vapor or E10 gasoline vapor for 6 hours per day, 7 days a week. Male and female rats were exposed separately for 70 days before mating, and together during mating for an additional 14 days. Once females were identified as being pregnant they were exposed until day 19 of their pregnancy, and then allowed to give birth. Five days after giving birth, both dams and pups were exposed till weaning on day 28. Exposure continued for male parental rats while females were pregnant and after birth until day 28. After weaning on day 29 male and female parents and all offspring were euthanized and reproductive parameters and general health of both the parents and offspring were assessed.

There were no adverse effects observed in the reproductive parameters examined in male or female rats exposed to baseline gasoline vapor or E10 gasoline vapor. In general health assessments, both baseline gasoline and E10 gasoline vapor exposure caused a decrease in body weight gain in male and female parents. Male rats exposed to vapor from baseline gasoline and E10 gasoline vapor displayed an increase in kidney weight and slight kidney damage, which is known to occur in male rats following exposure to hydrocarbons (Gray et al. 2014). Male rats exposed to 20,000 mg/m^3 E10 gasoline vapor had increased prostate weights as compared to male rats exposed to clean air only. The increase in prostate weight was not accompanied by any tissue damage, and was not, by the study authors, considered toxicologically adverse (Gray et al. 2014). In offspring, no adverse effects were observed from exposure to either baseline gasoline or E10 gasoline vapor (Gray et al. 2014). Based on these results, the researchers concluded that gasoline vapors are not selective reproductive toxicants and that "inclusion of oxygenates with gasoline does not appear to alter the minimal effects of exposure to gasoline evaporative emissions alone" (Gray et al. 2014).

3. API toxicity studies in adult animals

In adult male and female rats an inhalation study was conducted to determine whether gasoline vapor from either gasoline alone or gasoline containing oxygenates such as ethanol causes health effects in adult animals after repeat exposures over a period of weeks.   In this study both male and female adult rats were exposed to clean air only or 2,000, 10,000 or 20,000 mg/m^3 baseline gasoline vapor or E10 for 6 hours per day, 5 days a week for either 4 or 13 weeks. Immune function and genetic alterations were measured in the group of rats exposed for 4 weeks, and general physiological and neurological tests performed with the 13 week exposure group.

Following 4 weeks of exposure, tests of the immune system indicated that females rats exposed to the highest concentration of E10 gasoline vapor had weakened immune responses. Immune responses in female rats are typically more robust, and more sensitive to toxic insults than those in male rats. Thus, female rats are a better model for detecting potentially sensitive changes in immune responses (White et al. 2014). Overall, the study authors conclude that as compared to baseline gasoline vapor, gasoline vapor containing ethanol can suppress specific immune responses in female rats (White et al. 2014).

Tests to examine specific genetic changes performed on the group of rats exposed for 4 weeks produced largely negative results. Similar negative results for genetic alteration tests were seen in rats exposed to vapor from gasoline containing different oxygenates. Collectively, the researchers concluded that “the presence of oxygenates blended with gasoline do not increase genetic expression induced by gasoline evaporative emissions alone and present minimal likelihood of significant cytogenetic hazard” (Schreiner et al. 2014).

In the 13-week exposure group general health assessments were performed. While there were some small changes in body weight and kidney weight seen in the E10 vapor exposure groups, the study authors state that “it can be concluded that the addition of the oxygenates evaluated in this study did not significantly alter the subchronic toxicity of evaporative emissions compared to that of gasoline alone” (Clark et al. 2014).

There were no significant changes seen in a battery of neurological tests performed following 13 weeks of exposure. The only significant change with exposure to E10 gasoline vapor was an increase in a protein associated with potential neurotoxicity in the brains of male rats (but not female animals). However, the study authors suggest that the increased protein levels in male rat brains exposed to E10 gasoline vapor are only slightly higher than background levels, and are much lower that what typical neurotoxicant compounds can induce. Additionally, no changes in biomarker levels were seen in female rats. Overall, they conclude “that inhalation exposures for 13 weeks to gasoline vapors and vapors from gasoline combined with fuel oxygenates studied is largely without effect on morphological, functional and biochemical indices of neurotoxicity” (O’Callaghan et al. 2014).

D. Chu and colleagues adult animal exposure study

In the Chu et al. 2005 exposure study, adult male and female rats were exposed to clean air, or vapor from gasoline only (500 ppm), ethanol only (6,130 ppm) or a mixture of E85 and E15 (6,130 ppm ethanol/500 ppm gasoline). Exposures were carried out in inhalation chambers for 6 hours per day, 5 days per week for 4 weeks. After the 4 week exposure, general health and physiological and neurological parameters were assessed. An additional recovery group of both male and female rats were examined following a 4 week recovery phase after the initial 4 week exposure period.

While there were several significant changes observed across the range of parameters tested, the authors note that most of the changes were due to exposure to gasoline vapor only (Chu et al. 2005). Most of the observed effects following 4 weeks of exposure were reversed and not observed in the recovery groups (Chu et al. 2005). Although some additive or synergistic effects were noted with exposure to vapor from E85 and E15 gasoline, the authors conclude that “Effects observed following exposure to these two compounds were generally mild and adaptive in nature, and after cessation of exposure they return to normal” (Chu et al. 2005).

General Conclusions

Overall, there were few effects observed in animals exposed to evaporative emissions from either conventional gasoline or gasoline containing ethanol. The developmental effects observed from inhalation exposure to 100% ethanol vapor during pregnancy were mild, even at very high chamber air concentrations relative to expected human exposures, and were not consistent with those observed for oral exposure to ethanol during pregnancy in animals. Gasoline vapor is a complex mixture of hydrocarbons, and exposure to this vapor itself did cause some observable effects in animal studies. However, the presence of ethanol in gasoline vapor did not clearly exacerbate or otherwise change these effects.

One potentially important – and unique – finding was the association of E10 gasoline vapor with a decreased immune response in female rats in the API adult animal exposure study. Although several other studied oxygenates caused a similar immune suppressive effect, there was no change in immune response observed with exposure to E0 gasoline vapor. Thus, this effect could be attributable to the ethanol content of the E10 gasoline vapor. The USEPA reviewed this study as part of their approval process for E15 gasoline use (USEPA 2012). USEPA concluded that, as this effect was observed at an exposure concentration of 20,000 mg/m^3, but was not observed at an exposure concentration of 10,000 mg/m^3, the threshold for the effect (also known as the No Observable Adverse Effect Level, or NOAEL) is effectively 10,000 mg/m^3. Even after accounting for the fact that 10% of the fuel vapor is ethanol, this NOAEL is still several thousand times higher than the highest concentration of ethanol vapor measured during refueling with ethanol-containing gasoline, suggesting that real-world exposures would have no immune effects (USEPA 2012).

7. Conclusions

A review of several government initiated studies and numerous published scientific papers support the conclusion that widespread use of E10 fuel has no substantial public health impact as compared to conventional fuel, and may even have a small net benefit to public health. There is clear evidence that burning of E10 fuel modifies vehicle emissions, and some pollutants are increased while others are decreased. However, the modeling work predicts that the net resulting impact on ambient air quality, and thus health impact, is relatively small.

There is less information available regarding potential impacts of fuel blended with higher levels of ethanol (e.g., E15, E20, E85). The available studies suggested that increasing the percent of ethanol in blended fuels would increase emissions of hydrocarbons (including ethanol), nitrogen oxides, and particulate matter, while decreasing emissions of carbon monoxide. These studies also indicate that increasing ethanol content would increase emissions of acetaldehyde, formaldehyde, and acrolein, but would not cause any substantial change in emissions of benzene or 1,3-butadiene. Modeling studies and limited monitoring data suggest widespread use of high ethanol blends (e.g.,E85 fuel) may increase ambient air levels of ozone and associated public health impacts (increases in mortality, hospitalizations, and emergency department visits).

Recently completed animal studies have largely addressed a knowledge gap regarding potential health impacts of inhaled ethanol (versus ingested ethanol). These data will allow more quantitative evaluation of potential health impacts from increased ethanol exposure from use of ethanol-blended fuels. Results from animal studies suggest there is a large margin of exposure (i.e., margin of safety) between ethanol air levels shown to cause health effects in animal studies and estimated high-end exposures to ethanol while refueling or driving.

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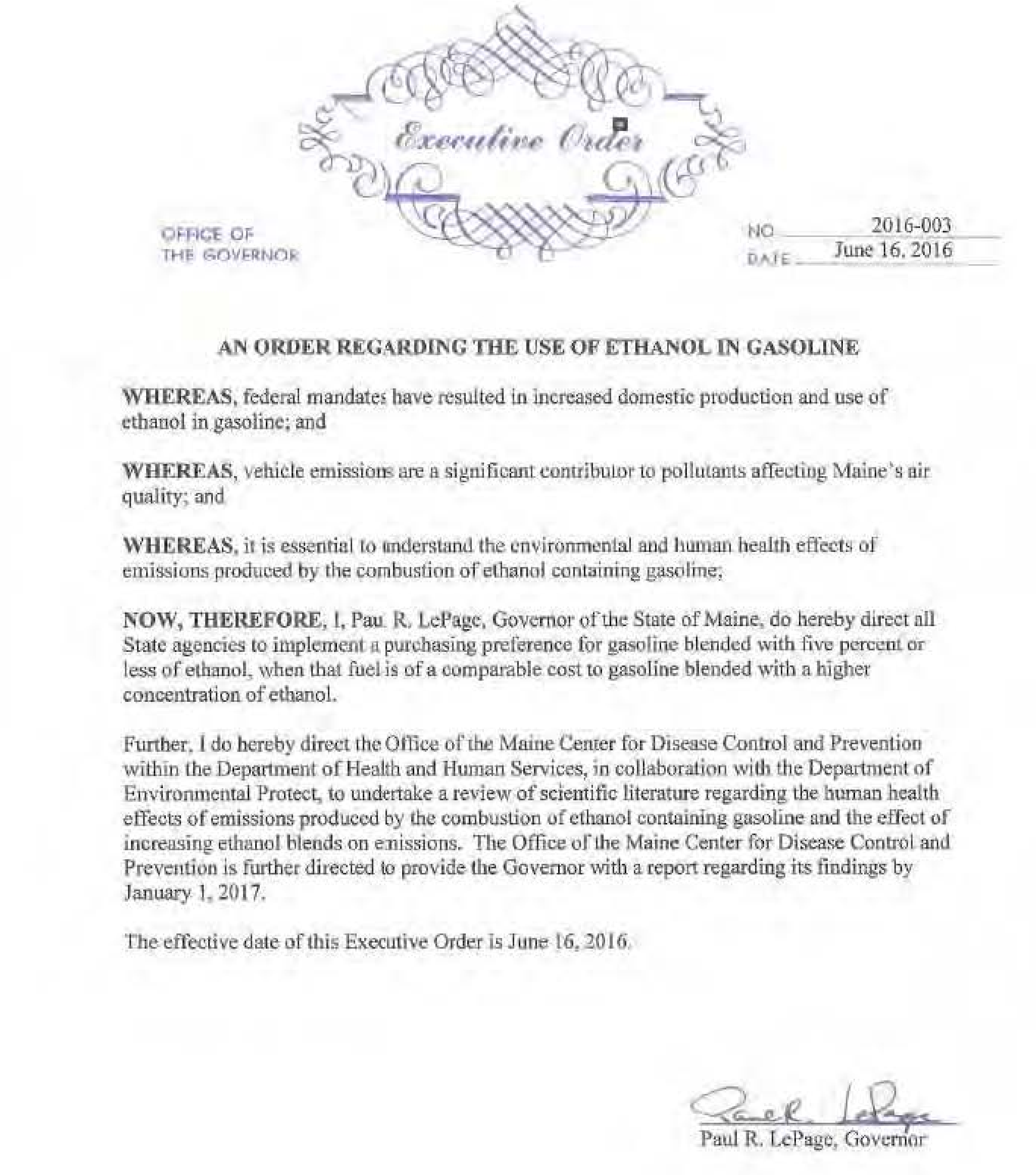
9. Executive Order



Executive Order

OFFICE OF
THE GOVERNOR

NO. 2016-003
DATE June 16, 2016

AN ORDER REGARDING THE USE OF ETHANOL IN GASOLINE

WHEREAS, federal mandates have resulted in increased domestic production and use of ethanol in gasoline; and

WHEREAS, vehicle emissions are a significant contributor to pollutants affecting Maine's air quality; and

WHEREAS, it is essential to understand the environmental and human health effects of emissions produced by the combustion of ethanol containing gasoline;

NOW, THEREFORE, I, Paul R. LePage, Governor of the State of Maine, do hereby direct all State agencies to implement a purchasing preference for gasoline blended with five percent or less of ethanol, when that fuel is of a comparable cost to gasoline blended with a higher concentration of ethanol.

Further, I do hereby direct the Office of the Maine Center for Disease Control and Prevention within the Department of Health and Human Services, in collaboration with the Department of Environmental Protect, to undertake a review of scientific literature regarding the human health effects of emissions produced by the combustion of ethanol containing gasoline and the effect of increasing ethanol blends on emissions. The Office of the Maine Center for Disease Control and Prevention is further directed to provide the Governor with a report regarding its findings by January 1, 2017.

The effective date of this Executive Order is June 16, 2016.

Paul R. LePage, Governor