Evaluation of the Health Effects From Exposure to Gasoline and Gasoline Vapors

Final Report

Executive Summary

NESCAUM

Northeast States for Coordinated
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EXECUTIVE SUMMARY

Introduction

In response to a 1985 request by the Directors of the Northeast States for Coordinated Air Use Management (NESCAUM), this document was prepared to assess the public health risks of occupational and non-occupational exposure to unleaded gasoline. Public health risks depend upon the presence of two necessary conditions: toxicological potency and the potential for exposure.

This assessment estimates exposure of service station attendants, self-service customers, and nearby residents to gasoline vapor emissions associated with service station operations. Estimates are also determined for residents exposed to gasoline contaminated drinking water and gasoline vapors which have migrated below ground into their homes from leaking underground storage tanks. A review of the toxicological data is also conducted in order to assess the health significance of these exposures.

Over the past several years, several of the Northeast states have developed expertise in toxicology and risk assessment. Although there is agreement among the states concerning several areas of risk assessment, the NESCAUM states recognize that risk assessments completed by agencies may differ from one another in their interpretation of toxicological or exposure data. In addition, our understanding of gasoline-induced health effects is likely to increase as more health data become available on the mixture, and as improved techniques are developed for assessing these data. Given these considerations, this document has been developed as a tool for assisting states in their management of gasoline-related health risks, and with the expectation that its findings may be modified to accommodate the various risk assessment and management approaches that exist among the states within the region.

Approach

Standard risk assessment methods were adopted in this assessment, although it was necessary to modify these methods because of limited toxicological data on the mixture and the variability of the composition of the mixture after it is released into the environment. This assessment of gasoline includes studies on the entire mixture, particular fractions of the mixture, and specific components (benzene, toluene, and xylene) which are considered to have the greatest health impacts.

Literature searches of available toxicological databases for gasoline, benzene, toluene, and xylene were conducted. In addition, secondary literature, primarily developed by the U.S EPA, was reviewed and utilized. Abstracts of human and animal studies are

organized according to acute, subacute and subchronic and chronic toxicity; reproductive and developmental toxicities; genetic toxicity, and carcinogenicity. Potential effects on ecosystems are also considered.

Exposure Assessment

Gasoline is a complex mixture of hydrocarbons and additives; the relative concentration of gasoline components is dependent upon the crude oil source, refinery process and product lines. Gasoline consists principally of paraffins (66 to 69 percent), aromatics (24 to 27 percent), and olefins (6 to 8 percent). Chemicals are added to improve engine performance. Gasoline exists in the environment in four states: as a free-moving liquid, adsorbed into soil, in groundwater, and as an aerosol or vapor. Gasoline components partition in environmental media according to vapor pressure, water solubility and partition coefficients. Because benzene, toluene and xylene have high vapor pressure and water solubility, they may exist in both the vapor phase and water soluble fraction of gasoline.

The six exposure scenarios selected for analysis are:

Scenario 1: a self-service customer at a service station inhaling gasoline vapors.

Scenario 2: a full-time service station attendant inhaling gasoline vapors.

Scenario 3: an individual residing downwind of a nearby service station inhaling gasoline vapors arising from gasoline pumps.

Scenario 4: an individual residing near a service station inhaling gasoline vapors arising from a leaking underground storage tank.

Scenario 5: an individual residing near a service station ingesting gasoline contaminated well water.

Scenario 6: an individual residing near a service station inhaling vapors which arise indoors from use of contaminated well water and dermal contact with contaminated water (e.g., showering).

The primary source of data for Scenarios 1 and 2 are monitoring studies of self-service customers and service station attendants during refueling operations. Sources of

gasoline vapors at service stations include losses from underground tanks, displacement vapor losses from filler pipes during refueling, fuel spillage and evaporative and tailpipe emissions from motor vehicles. Therefore, self-service customers are exposed to gasoline vapors both during refueling operations and other time spent at the service station. Service station attendants spend a full workday exposed to gasoline vapors from these sources. Residents living downwind of a service station may be continuously exposed to these emissions, but at significantly lower concentrations. In the case of residential exposure, dispersion modelling is used to estimate ambient concentrations from service station emissions. Because conditions associated with leaking underground storage tanks can vary significantly from case-to-case, quantification of exposures is based on limited case study information. Estimates for exposure and associated risks for any given site need to be determined on a site-specific basis.

Hazard Identification

General exposure parameters were employed for adult and infant weight, and corresponding ingestion and inhalation rates. Exposures associated with various exposure durations, expressed as mg/kg/day, are calculated for each exposure scenario in order to compare these exposures to toxicological criteria. Doses are calculated based on total ventilation for pulmonary effects and alveolar ventilation for systemic effects. Using alveolar ventilation as the basis for calculating systemic doses assumes that only the two-thirds of the inhaled dose that reaches the alveoli is absorbed into the systemic circulation. Non-ingestion exposure to gasoline contaminated water suggests a 2:1 non-ingestion to ingestion ratio; exposure from non-ingestion sources (e.g., showering, dish-washing) are comparable to and may be twice as much as the dose received from ingestion of 2 liters of contaminated water per day.

The available toxicokinetic data on gasoline, while limited, show that gasoline is absorbed from all exposure routes, including perinatal. The dermal route appears to be slower than oral and inhalation routes. Some gasoline components are absorbed more rapidly than others. For example, aromatic compounds (e.g., benzene, toluene, and xylene) which have both high blood/air partition coefficients and skin penetration rates, are absorbed more rapidly than other gasoline components. Metabolic pathways for benzene, toluene and xylene are defined, but the toxic metabolites are not well understood. Interactive effects at ambient exposure concentrations have not been characterized for these compounds.

General Toxicity

The toxicity of gasoline, benzene, toluene and xylene has been investigated in both short- and long-term exposure studies. The human studies generally involve acute environmental (accidental and deliberate inhalation) and acute and chronic occupational exposures to gasoline or to a mixture of gasoline components (particularly the aromatic compounds). Studies on laboratory animals have focused on the subacute and subchronic effects from exposure to gasoline and its major constituents (benzene, toluene, and xylene).

Acute exposure to gasoline and benzene, toluene, and xylene has been associated with skin and sensory irritation, central nervous system depression, and effects on the respiratory system. Prolonged exposures to these compounds also effects these organs as well as the kidney, liver and blood systems. In general, the effects that have been identified following gasoline exposure have also been identified for one or more of the specific components of gasoline evaluated in this assessment. For example, all substances have been shown to be neurotoxic and studies that indicate that gasoline is hemotoxic are supported by the abundant literature on benzene hematotoxicity.

The primary effects reported in several animal studies after protracted exposure to gasoline vapors are pulmonary toxicity and nephrotoxicity. The studies investigating the nephrotoxic effects in rats suggest a sex and species specific effect primarily from exposure to the branched alkanes (e.g., trimethylpentane); however, renal changes have occasionally been reported in female rats and mice exposed to certain distillate fractions of gasoline. Thus, the nephrotoxic response observed in rodents may be influenced by several factors including the exposure mixture, test protocol and/or the preferential distribution of the gasoline components to the kidney. The exposure related lesions consist of increase foci of regenerative epithelium in the renal cortex and dilated tubules at the corticomedullary junction.

Reproductive and Developmental Effects

Reproductive and developmental effects are among the most sensitive non-cancer toxic endpoints for benzene, toluene, and xylene exposures. These effects include increased resorptions, reduced fetal body weight, and delayed skeletal development, and in the case of benzene, induced bone marrow suppression in offspring. Benzene and xylene have been shown to be teratogenic in rats at maternally toxic doses after inhalation and oral exposure. Cleft palates in mice were also observed after oral exposure to xylene. In the only reported teratogenicity study in animals exposed to gasoline vapors, reduced size of fetuses in the high dose group was reported. Anecdotal data link chronic gasoline vapor

exposure of pregnant mothers to congenital central nervous system effects in their children. Menstrual disorders in female workers exposed to gasoline vapors have also been reported.

Genetic Toxicity

Unleaded gasoline, benzene, toluene and xylene have been evaluated for genotoxic effects in a variety of test systems. Generally, unleaded gasoline is not mutagenic in bacterial systems while positive results have been recorded for sex-linked mutations in *Drosophilia malangaster*, forward mutations with mouse lymphoma cells and induction of unscheduled DNA synthesis. Chromosomal aberrations were observed in humans exposed to gasoline vapors, although additional exposures confound the results of this study. Benzene is clastogenic, particularly in mammalian cells. Toluene and xylene studies are judged to be equivocal with negative evidence for mutagenicity and evidence of chromosomal aberrations in rat bone marrow cells and workers exposed to these gasoline components.

Carcinogenicity

One adequate carcinogen bioassay has been conducted with gasoline vapors. In that study, statistically significant increases in kidney tumors in male Fischer 344 rats and hepatocellular tumors in B6C3F1 mice were observed. Major uncertainties are (1) the vapor composition in this study was different from the ambient human environment and (2) the kidney tumors observed in male rats may be the result of a mechanism specific to the male rat and not female rats or other species. The male rat appears to selectively distribute the hydrocarbons (e.g., 2,2,4-trimethylpentane) believed responsible for the nephrotoxicity to the kidney. The female rat distributes significantly less of the hydrocarbon dose to the kidney as the male rat. This may account for the higher sensitivity in the male rat and weaker response in the female rat. The development of renal tumors as a result of nephrotoxicity has not been demonstrated in the rat. Thus, insufficient data are available on the mechanism of male rat kidney tumors to discount the positive carcinogenicity data from this bioassay. Carcinogenicity has been corroborated in more than one study, by multiple routes of exposure, and in at least two species of laboratory animals. Therefore, it is the finding of this assessment that animal bioassays provide sufficient basis for presuming gasoline to be a probable human carcinogen.

An association between benzene exposure and hematopoietic tumors has been found in human epidemiological studies. Hematopoietic system neoplasms, mainly leukemias and lymphomas, are associated with rodents exposed to benzene via the oral and inhalation routes. Other neoplastic lesions associated with exposure to benzene include

carcinomas of the mammary glands, Zymbal gland, skin, oral cavity, nasal cavity, lungs, and preputial gland; adenomas of the harderian gland and lungs; papillomas of the skin and oral cavity; and tumors of the forestomach, liver, lungs and ovaries. Available data are inadequate to determine the carcinogenicity of toluene or xylene.

Epidemiologic studies of unleaded gasoline are not available because insufficient time has elapsed since its introduction in the mid-1970s. The results of epidemiologic studies of typical gasoline exposure provide limited evidence for carcinogenicity in humans. In general, these studies were limited by deficiencies in quantitative exposure data and multiple exposure to other petroleum products and chemicals.

Risk Assessment

Toxicological potency of gasoline and the indicator compounds were evaluated with respect both to cancer and non-cancer effects. Assumption of non-threshold and low dose linearity for cancer risks from exposure to gasoline or benzene were characterized based upon the adoption of U.S EPA cancer potency values for unleaded gasoline and benzene.

This assessment has drawn a distinction between interspecies differences in toxicity and in delivered dose. When assessing the systemic effects observed in animal studies, human equivalent doses have been estimated by scaling the mg/kg/day animal doses by a factor based on metabolism (body weight raised to the three-quarters power). Further uncertainty factors were then applied to this dose in order to estimate a no effect level for threshold effects in sensitive human populations.

In the quantitative assessment of non-cancer effects, critical studies were identified from the general toxicity, reproductive and developmental toxicity, and genetic toxicity chapters. Based on this evaluation, the most sensitive health effects associated with gasoline, benzene, toluene, and xylene were determined. These health effect endpoints included kidney toxicity (gasoline); genetic, hematopoietic, and developmental effects (benzene); neurotoxic effects (toluene); and reproductive and fetotoxic effects (xylene).

Comparisons of human equivalent doses for the lowest effect levels observed in animal studies show that sensitive toxicity endpoints for each substance reviewed in this assessment (gasoline, benzene, toluene, and xylene) are associated with fairly definable dose ranges. For gasoline, kidney toxicity is associated with human equivalent doses in the 2 to 4 mg/kg/day dose range. For benzene, hematotoxicity occurs in the dose range of 0.1 to 1.0 mg/kg/day. For toluene, thresholds for sensitive neurobehavioral, hematological, and immunological effects occur in the dose range of 0.5 to 1.5 mg/kg/day.

Following the identification of the most sensitive toxicological responses, the studies most appropriate for risk assessment based on study design and toxicological

relevance were selected for quantitative risk assessment. For non-cancer threshold effects, uncertainty factors were applied to account for interspecies differences between humans and laboratory animals, exposure durations and sensitive populations. The non-cancer reference doses for the most sensitive endpoints for gasoline, benzene, toluene, and xylene are presented in Table 1.

Risk Characterization

Estimated cancer and non-cancer risks for each of the six scenarios are based upon comparison of health criteria with estimated exposure doses. The health criteria for cancer effects are cancer potency values; the health criteria for non-cancer effects are reference doses (RfDs). Several uncertainties are associated with quantifying cancer and non-cancer risks to humans based upon data from animal bioassays and epidemiological studies. These uncertainties include: (1) estimates may exclude gasoline components of potential concern; (2) inaccuracies in the assumptions about the intensity and duration of exposure; (3) lack of information on interactive effects among constituents in the complex mixture, and (4) uncertainties associated with exposure of sensitive individuals, including pregnant women, the very young, and the old or infirm, as well as individuals who may suffer from chronic respiratory, immunological, or other predisposing illnesses. These and other uncertainties warrant the adoption of conservative assumptions, when possible, so that errors are made on the side of caution. A reflection of these uncertainties is provided by both average and upper limit exposure doses and health criteria.

Non-cancer health risks associated with gasoline exposure are presented in Table 2. The reference doses are: gasoline - 0.003 mg/kg/day; benzene - 0.004 mg/kg/d; toluene - 0.014 mg/kg/d and xylene - 0.034 mg/kg/day. Both mean and worst-case exposure assumptions yield estimates of exposure doses that are greater than reference doses derived in this assessment. Some margins of safety, however, exist with regard to specific indicator substances under all scenarios.

Potential individual lifetime (70 years) cancer risks associated with exposure to unleaded gasoline and benzene are presented in Table 3. These cancer risks are based on a cancer potency value of 0.0035 per mg/kg/day for gasoline and 0.026 mg/kg/day for benzene. The exposure doses corresponding to one in a million cancer risk for gasoline and benzene are estimated to be 2.8×10^{-4} mg/kg/day and 3.8×10^{-5} mg/kg/day, respectively. Based upon an evaluation of available data, toluene and xylene are assigned cancer potency values of zero. Maximum individual lifetime cancer risks associated with gasoline and/or benzene are estimated to be 3.5×10^{-4} under scenario 1, 3.6×10^{-3} under

TABLE 1

NON-CANCER REFERENCE DOSES FOR GASOLINE AND SELECTED INDICATOR CONSTITUENTS

substance (toxic endpoint)	Reference air levels (ug/m^3) adult	infant	Reference dose* (mg/kg/d)	Exposure Interval	Reference oral dose** (mg/L)
gasoline (kidney effects)	15	11	0.003	Subchronic	0.10
benzene (developmental effects)	19	-	0.004	Subacute	0.10
toluene (neurotoxicity)	68	52	0.014	Subchronic	0.5
xylene (reproductive effects)	165	-	0.034	Subacute	1.2

* based upon assumed weights and pulmonary ventilation rates (when applicable), as follows:

mouse: 0.025 kg, 0.029 cu M/day

rat: 0.25 kg, 0.14 cu M/day

monkey: 5 kg, 1.7 cu M/day

human: 70 kg, 21.6 cu M/day (pulmonary)
14.4 cu M/day (systemic)

infant: 10 kg; 4.0 cu M/day (pulmonary)
2.7 cu M/day (systemic)

** Oral references doses based on inhalation doses and consumption of 2 L water/day.

TABLE 2

POTENTIAL NON-CANCER RISKS ASSOCIATED WITH EXPOSURE TO GASOLINE AND SELECTED INDICATOR CONSTITUENTS

Exposure Scenario	Estimated exposure[a] (mg/kg/day) mean	maximum	Reference dose (RfD)[b] (mg/kg/d)	margin of safety (RfD/exp. dose) mean	maximum
scenario 1: self-service customer at gas station exposed via inhalation[1,3]					
gasoline	9.4×10^{-3}	1.0×10^{-1}	0.003	0.32	0.03
benzene	7.3×10^{-5}	7.2×10^{-4}	0.004	55	5
toluene	5.7×10^{-5}	4.9×10^{-4}	0.014	250	30
xylenes	2.2×10^{-5}	2.6×10^{-4}	0.034	1545	131
scenario 2: gas station attendant exposed via inhalation[1,3]					
gasoline	1.8	-	0.003	0.002	-
benzene	2.1×10^{-2}	1.4×10^{-1}	0.004	0.19	0.03
toluene	3.8×10^{-2}	-	0.014	0.4	-
xylenes	1.5×10^{-2}	-	0.034	2	-
scenario 3: resident living downwind of gas station exposed via inhalation[1,3]					
gasoline	3.1×10^{-3}	1.6×10^{-2}	0.003	0.97	0.19
benzene	2.6×10^{-5}	1.1×10^{-4}	0.004	154	36
toluene	6.2×10^{-5}	2.9×10^{-4}	0.014	230	50
xylenes	2.7×10^{-5}	1.3×10^{-4}	0.034	1260	262
scenario 4: resident inhaling vapors from nearby leaking underground storage tank[1,4]					
gasoline	-	-	0.003	-	-
benzene	3.6×10^{-1}	1.9	0.004	0.01	0.002
toluene	6.2×10^{-1}	5.9	0.014	0.02	0.002
xylenes	4.2×10^{-1}	3.6	0.034	0.08	0.0009
scenario 5: resident exposed to gasoline via ingestion of contaminated well water[2,4]					
gasoline	1.7×10^{-1}	2.9	0.003	0.02	0.001
benzene	1.4×10^{-2}	7.0×10^{-2}	0.004	0.29	0.06
toluene	8.0×10^{-3}	5.0×10^{-2}	0.014	1.8	0.3
xylenes	8.6×10^{-3}	4.0×10^{-2}	0.034	4	0.85

TABLE 2
(CONTINUED)

Exposure Scenario	Estimated exposure[a] (mg/kg/day) mean	maximum	Reference dose (RfD)[b] (mg/kg/d)	margin of safety (RfD/exp. dose) mean	maximum
scenario 6: resident exposed via inhalation and dermal contact during showering[1,4,5]					
gasoline	1.7×10^{-1}	3.4×10^{-1}	0.003	0.02	0.009
benzene	1.4×10^{-2}	2.8×10^{-2}	0.004	0.29	0.14
toluene	8.0×10^{-3}	1.6×10^{-2}	0.014	1.8	0.9
xylenes	8.6×10^{-3}	1.7×10^{-2}	0.034	4	2

[a] refer to Chapter 5
[b] refer to Table 11-4
[1] assumes inhalation of 14.4 cu M/d, 24 h/d
[2] assumes ingestion of 2 L water/day
[3] based upon arithmetic means of monitoring studies described in "Exposure Assessment"
[4] based upon limited case-study information. Estimated risks for any given site need to be determined on a site-specific basis.
[5] assumes mean values equal mean drinking water exposures, and upper limits equal twice drinking water maxima

TABLE 3

POTENTIAL CANCER RISKS ASSOCIATED WITH EXPOSURE TO GASOLINE AND SELECTED INDICATOR CONSTITUENTS

Exposure Scenario	Estimated exposure[a] (mg/kg/day) mean	maximum	Cancer Potency[b] (per mg/kg/d)	Estimated lifetime cancer risk[c] mean	maximum
scenario 1: self-service customer at gas station exposed via inhalation[1,3]					
gasoline	9.4×10^{-3}	1.0×10^{-1}	0.0035	3.3×10^{-5}	3.5×10^{-4}
benzene	7.3×10^{-5}	7.2×10^{-4}	0.026	1.9×10^{-6}	1.9×10^{-5}
toluene	5.7×10^{-5}	4.9×10^{-4}	-	-	-
xylenes	2.2×10^{-5}	2.6×10^{-4}	-	-	-
scenario 2: gas station attendant exposed via inhalation[1,3]					
gasoline	1.8	-	0.0035	6.3×10^{-3}	-
benzene	2.1×10^{-2}	1.4×10^{-1}	0.026	5.5×10^{-4}	3.6×10^{-3}
toluene	3.8×10^{-2}	-	-	-	-
xylenes	1.5×10^{-2}	-	-	-	-
scenario 3: resident living downwind of gas station exposed via inhalation[1,3]					
gasoline	3.1×10^{-3}	1.6×10^{-2}	0.0035	1.1×10^{-5}	5.6×10^{-5}
benzene	2.6×10^{-5}	1.1×10^{-4}	0.026	6.8×10^{-7}	2.9×10^{-6}
toluene	6.2×10^{-5}	2.9×10^{-4}	-	-	-
xylenes	2.7×10^{-5}	1.3×10^{-4}	-	-	-
scenario 4: resident inhaling vapors from nearby leaking underground storage tank[1,4]					
gasoline	-	-	0.0035	-	-
benzene	3.6×10^{-1}	1.9	0.026	9.4×10^{-3}	4.9×10^{-2}
toluene	6.2×10^{-1}	5.9	-	-	-
xylenes	4.2×10^{-1}	3.6	-	-	-
scenario 5: resident exposed to gasoline via ingestion of contaminated well water[2,4]					
gasoline	1.7×10^{-1}	2.9	0.0035	6.0×10^{-4}	1.0×10^{-2}
benzene	1.4×10^{-2}	7.0×10^{-2}	0.026	3.6×10^{-4}	1.8×10^{-3}
toluene	8.0×10^{-3}	5.0×10^{-2}	-	-	-
xylenes	8.6×10^{-3}	4.0×10^{-2}	-	-	-

TABLE 3
(CONTINUED)

Exposure Scenario	Estimated exposure[a] (mg/kg/day) mean	maximum	Cancer Potency [b] (per mg/kg/d)	Estimated lifetime cancer risk[c] mean	maximum
scenario 6: resident exposed via inhalation and dermal contact during showering[1,4,5]					
gasoline	1.7×10^{-1}	3.4×10^{-1}	0.0035	6.0×10^{-4}	1.1×10^{-3}
benzene	1.4×10^{-2}	2.8×10^{-2}	0.026	3.6×10^{-4}	7.3×10^{-4}
toluene	8.0×10^{-3}	1.6×10^{-2}	-	-	-
xylenes	8.6×10^{-3}	1.7×10^{-2}	-	-	-

[a] refer to Chapter 5
[b] U.S EPA Cancer Potency Values
[c] estimated lifetime (70 years) cancer risk = (estimated exposure dose) x (assumed cancer risk)
[1] assumes inhalation of 14.4 cu M/d, 24 h/d
[2] assumes ingestion of 2 L water/day
[3] based upon arithmetic means of monitoring studies described in "Exposure Assessment"
[4] based upon limited case-study information. Estimated risks for any given site need to be determined on a site-specific basis.
[5] assumes mean values equal mean drinking water exposures, and upper limits equal twice drinking water maxima

scenario 2; 5.6×10^{-5} under scenario 3; 4.9×10^{-2} under scenario 4; 1.0×10^{-2} under scenario 5, and 1.1×10^{-3} under scenario 6.

It should be noted that although the exposure doses for scenarios 4, 5, and 6 are based on data from limited case studies, significant risks may be associated with such exposures. Estimated risks for any given site, however, need to be determined on a site-specific basis.

It is concluded in this assessment that gasoline and at least one of its major constituents (benzene) are presumed human carcinogens. Exposure to gasoline and its components is also associated with other adverse health effects such as toxicity to the hematopoietic, kidney, liver, reproductive/developmental and nervous systems. Comparison of cancer and non-cancer health criteria show that non-cancer reference doses for gasoline and benzene correspond approximately to one cancer risk in one hundred thousand.

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