A Cautionary Tale:
How Even Knowledgeable Experts Can Be Misled by the Precautionary Principle

A Response to the Article:
"The Global Experience with Lead in Gasoline and the Lessons We Should Apply to the Use of MMT"

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Introduction

In a recent article, former U.S. Environmental Protection Agency (EPA) staffer and MacArthur Foundation award winner Michael P. Walsh advocates against the use of the octane-enhancing gasoline fuel additive known as MMT®.[1] Produced by Afton Chemical Corporation, the key ingredient of MMT® is the essential nutrient manganese. Although acknowledging that "the impact of MMT on human health, the environment, vehicles, and vehicle emissions *has been the subject of a great deal of research*," Mr. Walsh argues that the "precautionary principle" requires Afton "to demonstrate *conclusively* that [MMT®] is safe before it is sold around the world." (Emphasis added.) As support, Mr. Walsh cites purported "lessons learned" from the experience of using lead in gasoline, even though MMT® contains manganese, not lead.

Mr. Walsh's paper illustrates just how easily the precautionary principle can be misapplied, even by knowledgeable experts. In Mr. Walsh's case, he has erred in two fundamental ways. First, the paper ignores that a proper application of the precautionary principle ultimately depends upon a thorough and balanced assessment of the relevant science. At best, Mr. Walsh's paper presents an incomplete and skewed assessment of the science that falls far short of describing the full range of research and assessment of MMT® that has been completed while MMT® has been used in gasoline during the past three decades. Without a thorough and complete assessment of the science, the paper lacks the necessary basis for invoking the precautionary principle. Second, the paper advocates an unprecedented and unworkable interpretation of the precautionary principle, ignoring that no material in gasoline, including any of the alternatives to MMT®, has ever been shown to be "conclusively" safe. Because the combustion of gasoline, no matter how constituted, has inherent and unavoidable risk, the "conclusive" proof of safety sought by Mr. Walsh is simply not possible.

Gasoline Combustion and the Precautionary Principle

Gasoline combustion entails inherent risk. It results in the release of hundreds of substances that present a potential threat to human health or the environment. These substances include hydrocarbons, carbon monoxide, nitrogen oxides, particulate matter, and various greenhouse gases. Some of the materials emitted from gasoline-powered motor vehicles present risks because they undergo transformation in the atmosphere to form derivative products, such as ozone or fine particulates, that are known to harm human health or the environment. Other materials present risks because they are known to be toxic (or suspected to be) in their own right. These toxic materials may cause cancer or other non-cancer health or environmental impacts. Still other fuel components entail risk because they can alter the operation of systems on the vehicle designed to reduce emission by-products.

EPA recently compiled a master list of more than 1,000 compounds emitted from mobile sources.[2] From this list, EPA identified nearly 150 compounds that present potential cancer or non-cancer threats to human health or threats to the environment. Included among these compounds were metals, such as manganese, nickel, and chromium, and a wide range of hydrocarbons, including benzene, 1,3 butadiene, formaldehyde, acetaldehyde, acrolein, polycyclic organic matter (POM), and naphthalene, among others.

Many of the mobile source-related compounds identified by EPA as potential threats are found in gasoline. Benzene, acrolein and 1,3 butadiene are natural hydrocarbon components or combustion by-products of gasoline. Other compounds on EPA's list are combustion by-products of materials intentionally added to gasoline by refiners and gasoline blenders, including manganese from MMT®, acetaldehyde from MTBE, and formaldehyde from ethanol. (MMT®, MTBE, and ethanol are competing fuel additives used to increase octane.) The concentration of individual compounds found in gasoline typically varies, however, depending upon the range of options available to the gasoline producer. Concentrations vary because changes in one parameter of gasoline (e.g., benzene concentrations) often require parallel alterations in another parameter (e.g., increased use of ethanol, MTBE, or MMT®, or other fuel components) to ensure that gasoline meets consumer expectations for performance.

For this reason, responsible regulatory authorities have long recognized that decisions concerning gasoline composition must account for the full range of constituents in gasoline and how changes in one constituent may impact another. Language in the *U.S. Clean Air Act* provides a clear example:

> No fuel or fuel additive may be prohibited by the Administrator . . . unless he finds, and publishes such finding, that in his judgment such prohibition *will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited*.[3]

The same should be true for any potential application of the "precautionary principle" to decision making concerning the composition of gasoline. The precautionary principle is commonly understood to refer to a science-based framework for protecting human health or the environment. A widely cited example is found in the "Rio Declaration," which defines the principle as follows: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[4] This definition makes clear that the principle has application only if

(a) a threat to human health or the environment exists that is serious or irreversible;

(b) a sound scientific basis (short of "full scientific certainty") supports the existence of the serious or irreversible threat; and

(c) cost-effective measures exist to prevent the threat to human health or the environment.

As noted above, the "threat" to human health from gasoline combustion is multi-dimensional in nature. The removal or reduction of one potentially dangerous component of gasoline can prompt increased use of another potentially dangerous component. As a result, any application of precaution to deal with the threats presented by gasoline combustion must also be multi-dimensional. This is confirmed by recent guidance issued by the Government of Canada relating to the application of "precaution" in scientific decision making. The Canadian guidance highlights the critical importance of "comparative" assessments whenever trade-offs must be made.

> Precautionary measures should be cost-effective, with the goal of generating (i) an overall net benefit for society at least cost, and (ii) efficiency in the choice of measures . . . *Consideration of risk-risk tradeoffs or comparative assessments of different risks would generally be appropriate. . . .*[5]

In short, a multi-dimensional threat like that presented by gasoline combustion requires a multi-dimensional risk assessment framework, even when pursuing action in a precautionary way. The adoption of a precautionary approach to any single component of gasoline *without proper consideration of the multi-dimensional nature of the threat posed by gasoline combustion* may have the unintended result of increasing overall risks to public health or welfare. Yet that is precisely what Mr. Walsh's paper proposes. The paper fails to acknowledge, much less address, the inevitable trade-offs that must be made when evaluating the comparative risks and benefits of different fuel formulations. Instead, Mr. Walsh focuses exclusively on MMT® and simplistically asserts, without any authoritative legal or policy support and based on a skewed and incomplete assessment of the relevant science, that his conception of the precautionary principle requires Afton "to demonstrate *conclusively* that MMT® is safe *before* it is sold around the world." (Emphasis added.) As explained more fully below, the approach advocated by Mr. Walsh is flawed both in concept and in its execution.

The Proposed Application of the Precautionary Principle Is Flawed

I. MMT® Has Been the Subject of Numerous Technical Reviews.

Contrary to what Mr. Walsh implies, MMT® is not a new fuel additive. It has been available for use for decades. In Canada, for example, vehicles equipped with advanced emission control systems (as they have evolved over time) have operated on gasoline containing MMT® for nearly three decades. At present, the producer of MMT® reports that more than 150 refineries located in more than 45 countries around the world are using MMT®.[6] The widespread and growing use of MMT® would be surprising and a potential and justifiable target of the precautionary principle if, as Mr. Walsh argues, little was known about MMT® and its potential impacts on public health or vehicle operation. In fact, however, MMT® has been the subject of an enormous number of scientific studies and technical reviews over the past three decades. As a result, much is already known about MMT®, both with respect to potential impacts on public health and how MMT® interacts with vehicle emission control systems.

A. MMT® and Public Health

The scientific record for MMT® and its potential impact on public health is voluminous. For this reason, reasonable scientific judgments about the safety of MMT® can readily be made, especially in comparison to other additives and components of gasoline such as benzene, 1,3-butadiene, MTBE, and ethanol. For example, when assessing MMT® in December of 2001, Health Canada concluded that it "has no objection to the use of MMT."[7] Health Canada explained that, "based on its assessment of the scientific evidence . . . the amount of scientific information on the neurotoxicity of and exposure to manganese is substantial compared to the equivalent information on the toxicity and potential exposures associated with some of the alternatives."[8] Table 1 provides the central conclusions of numerous assessments of MMT® that have been conducted by regulatory authorities around the world over 30+ years of MMT®'s use.

Table I. Conclusions from 30+ Years of MMT® Health Reviews

Study or Review	Conclusion
EPA, 1973	"There is a reasonable margin of safety with use of manganese in gasoline" because "available evidence indicates that dosages required to produce … adverse effects are several orders of magnitude above those that would be present in ambient air as a result of even the widespread use of manganese as a gasoline additive."
EPA, 1975	"There is no evidence that predicted manganese concentrations resulting from the use of [MMT] would result in adverse health effects."
Health and Welfare Canada, 1978	"[T]here is no evidence at present to indicate that expected ambient manganese concentrations would constitute a hazard to human health."
Australia, 1987	"[T]here were no toxicological concerns over the use of MMT in petrol."
EPA, 1994	"Although it is not possible based on the present information to conclude whether specific adverse health effects will be associated with manganese exposures in the vicinity of or exceeding the RfC, neither is it possible to conclude that adverse health effects will not be associated with such exposures." The additional testing proposed by EPA will therefore "provide *greater assurance* that manganese emissions from MMT use will not jeopardize public health." (Emphasis added.)
Health Canada, 1994	"It has therefore been concluded that airborne manganese resulting from the combustion of methylcyclopentadienyl manganese tricarbonyl (MMT) in gasoline powered vehicles is not entering the Canadian environment in quantities or under conditions that may constitute a health risk."
Health Canada, 1998	"[T]here is no new scientific evidence to modify the conclusions drawn by Health Canada in 1994 that MMT® poses no health risk."
United Kingdom, 1999	"[T]he increase in the ambient concentrations of manganese [from MMT use] was unlikely to constitute a risk to health … "
South Africa, 2000	"[T]he introduction of MMT® in petrol in South Africa would have an insignificant effect on health risks relating to community exposure to manganese in airborne emissions from vehicle tailpipes" and "would make a very low contribution to the overall exposure of communities to manganese."
Health Canada, 2001	"[B]ased on its assessment of the scientific evidence, Health Canada has no objection to the use of MMT."
NICNAS, 2003 (Australia)	"[T]he overall risk to public health from the use of MMT [as an anti-valve seat recession (ASVR) fuel additive] . . . is low." Further, "overall chronic Mn exposures (from all sources combined) are unlikely to change significantly."

B. MMT® and Vehicle Performance

The scientific record for MMT® and its potential impact on vehicle performance is also voluminous. In addition to numerous vehicle fleet tests conducted by automakers, the producer of MMT®, and others, the impact of MMT® on the operation of the major components of vehicle engine and emission control systems (i.e., spark plugs, fuel injectors, intake and exhaust valves, catalytic converters, and oxygen sensors, etc.) has been the subject of a wide range of studies. MMT® also has a long and established record of acceptable performance in commercial use in Canada, the U.S. and elsewhere around the world. As in the case of potential public health concerns, more than ample scientific data exist to make reasonable scientific judgments about MMT®'s compatibility with advanced vehicle emission control systems. A summary of some of the key conclusions of the numerous technical reviews of MMT® that have occurred over the past several decades is presented in Table II.

Table II. Conclusions from 20+ Years of MMT® Auto Impact Reviews

Study or Review	Conclusion
Royal Society of Canada, 1986	"[T]he current-technology catalysts are unlikely to be damaged or rendered inoperative by the use of [MMT®]."
Canadian General Standards Board, 1986	"The use of MMT at current CGSB levels [i.e., up to 0.018 gram manganese per liter] does not significantly compromise emission-control system operation or component durability."
Environment Canada, 1990	Although the incidence of catalyst failure in Canada "is difficult to enumerate," an "examination of the manufacturer's claims did not reveal any abnormal incidence of [converter] plugging."
EPA, 1994	"Based on all of the information [] available concerning the potential effect of use of MMT in unleaded gasoline on regulated emissions, as submitted by Ethyl and others, the Administrator of EPA determined . . . that, 'Ethyl has satisfied its burden under Clean Air Act 211(f)(4) to establish that use of [MMT®] at the specified concentration will not cause or contribute to a failure of any emission control device or system (over the useful life of any vehicle in which such device or system is used) to achieve compliance by the vehicle with the emission standards with respect to which it has been certified.'"
Environment Canada, 1998	"To date, there has been no reported widespread impact on catalysts, OBDs or any other emissions control related component or any warranty related problems in Canada due to the use of MMT." "In March [1998], representatives of domestic and foreign automakers told us that preliminary results of their latest studies could *not* confirm that MMT® impairs the proper functioning of on-board diagnostic systems nor that MMT® jeopardizes their ability to comply with current vehicle emission standards."
China SEPA, 2006	The "[c]ombustion of MMT® does not have adverse effect, without causing plugging."

In short, MMT® has been the subject of extensive and essentially continuous review since the product first began to be used in gasoline in the 1970s. This review process has resulted in the generation of an enormous amount of information concerning MMT® and its impact on vehicle operation and the public health and welfare. The sheer enormity of the database provides a measure of certainty to conclusions pertaining to MMT® and its potential value as a gasoline blending component that few, if any, other components of gasoline can match.

II. Mr. Walsh has proposed an impractical and unworkable "precautionary principle" for assessing the risks from gasoline combustion.

Mr. Walsh's reliance upon the precautionary principle as a basis for restricting use of MMT® is misplaced for three reasons. First, Mr. Walsh cannot establish -- as he must to invoke the precautionary principle -- that use of MMT® presents a serious or irreversible threat to human health or the environment. As noted above, MMT® has been the subject of numerous, comprehensive reviews by scientific bodies and regulatory authorities for more than three decades. These reviews have substantiated that MMT® is an acceptable fuel additive for use in gasoline. MMT®'s record of safe and effective use in commercial operation corroborates the results of the numerous reviews. Mr. Walsh's paper nowhere acknowledges MMT®'s extensive review history, nor the implications of the conclusions of those reviews (or the decades of safe and effective commercial use around the world) to the application of his concept of the precautionary principle.

Second, Mr. Walsh's paper does not reflect sound science. Sound science requires that all relevant data be evaluated and considered in context. The paper selectively presents descriptions of the results of some studies without examining the full array of studies relevant to any assessment of MMT®'s potential impacts on public health or vehicle operation. Concerning MMT® and public health, for example, Mr. Walsh ignores a substantial body of new studies mandated by EPA to assist EPA refine its risk assessment for manganese. (This new body of studies, which is nearing completion, is available on the internet at www.regulations.gov identified by docket number EPA-HQ-OAR-2004-0074.) Figure 1 presents results of a manganese inhalation study conducted in young male Rhesus monkeys as part of this new body of work. It confirms that the body's natural systems for controlling how ingested manganese is distributed throughout the body *also control how inhaled manganese is handled*. This is an important finding because it means that the body is able naturally to accommodate substantial changes in low-level exposure to airborne manganese -- just as it can in the case of ingested manganese -- without any corresponding change in manganese tissue concentrations. Tissue concentrations begin to change only at levels of airborne manganese exposure *that are several orders of magnitude higher than the range of existing inhalation reference concentrations for manganese*.

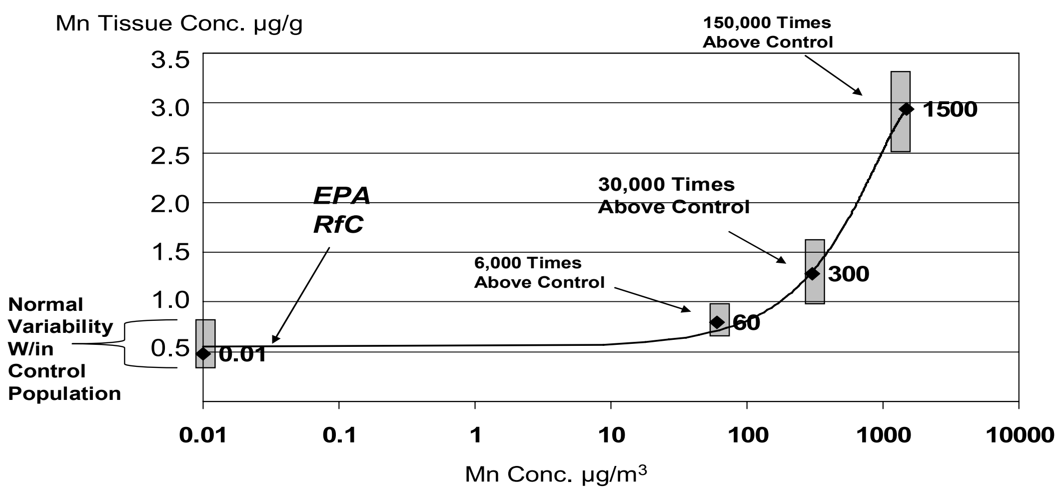

Figure 1. The relationship of manganese in air concentration to manganese tissue concentration in the globus palladus of young male Rhesus monkeys.

Similarly, Mr. Walsh urges precaution because automakers have expressed "[c]oncerns with the impact of MMT® on vehicle emissions," noting that such concerns "have already begun to emerge in the developing world." That the automakers have concerns about use of MMT® is nothing new. The many technical reviews of MMT® that have occurred over the past two decades have been undertaken specifically to address the merit of the automaker's concerns. Those concerns are essentially the same today as they were two decades ago and they have repeatedly been shown to be baseless. Although Mr. Walsh's paper refers to a major vehicle fleet study reported in 2002 by the automakers to support a formal request that MMT® be banned in North American gasoline, Mr. Walsh omits any reference to the substantial body of peer-reviewed technical work showing that the automaker study *actually reaffirms that MMT® is a safe and effective gasoline fuel additive*.[9] Also telling, Mr. Walsh's paper omits noting that regulatory authorities in North America have opted during the five years since release of the automaker study and related papers (such as the Ford Escort paper to which Mr. Walsh also refers) *not to alter the longstanding conclusion that MMT® is an acceptable fuel additive for use in gasoline*. Selective presentation of data and mistaken assertions do not provide the requisite scientific basis for invocation of the precautionary principle.

Third, Mr. Walsh's paper fails to demonstrate that cost-effective measures can be employed in place of MMT® to prevent risk to public health or the environment. As noted at the beginning of this paper, the threat to human health and the environment presented by gasoline combustion is multi-dimensional in nature. Contrary to Mr. Walsh's claims, MMT® is not the only source of potential risk, nor is it the most serious. In a recent EPA action, EPA identified seven gasoline emission by-products to be of "particular concern."[10] As shown in Table III, MMT® and manganese are <u>not</u> on EPA's list.

Table III. Mobile Source Air Toxics Identified by EPA to Be of Particular Concern.

Component	Health Threat
Benzene	"The EPA's IRIS database lists benzene, an aromatic hydrocarbon, as a known human carcinogen (causing leukemia) by all routes of exposure. A number of adverse noncancer health effects including blood disorders and immunotoxicity have also been associated with long-term occupational exposure to benzene."
1,3 Butadiene	"EPA has characterized 1,3-butadiene, a hydrocarbon, as a leukemogen, carcinogenic to humans by inhalation."
Formaldehyde	"Since 1987, EPA has classified formaldehyde, a hydrocarbon, as a probable human carcinogen based on evidence in humans and in rats, mice, hamsters, and monkeys."
Acetaldehyde	"Acetaldehyde, a hydrocarbon, is classified in EPA's IRIS database as a probable human carcinogen and is considered toxic by inhalation."
Acrolein	"Acrolein, a hydrocarbon, is intensely irritating to humans when inhaled, with acute exposure resulting in upper respiratory tract irritation and congestion."
Polycyclic Organic Matter (POM)	"Many of the compounds known as POM are classified by EPA as probable human carcinogens based on animal data."
Naphthalene	"IRAC has reevaluated naphthalene and re-classified it as a Group 2B: possibly carcinogenic to humans."

Regarding manganese, EPA noted only that it is currently generating information needed "to update an assessment of the potential human health risks related to having manganese in the national fuel supply."[11]

When MMT® is available as a fuel blending option, manganese is an unavoidable emission by-product, but refiners and gasoline blenders can reduce or eliminate other components in gasoline that increase the emission of one or more of the substances identified by EPA to be of most "concern." When MMT® is not an option, the converse is true. Refiners and gasoline blenders must use alternative blending components, such as MTBE or ethanol, that increase emissions of one or more of the listed substances. In short, trade-offs are inevitable when formulating gasoline. For reasons that are not clear, Mr. Walsh's paper inexplicably ignores these inevitable trade-offs. Instead, Mr. Walsh argues that "conclusive" proof of safety should be the standard for MMT® without any acknowledgement, much less evaluation, of the risks presented by the alternatives to MMT®. And in a particularly ironic twist, Mr. Walsh's paper advocates the "conclusive" proof of safety standard for MMT® even in the case of leaded gasoline (the continued use of which Mr. Walsh bemoans) notwithstanding that use of MMT® has proven to be one of the quickest and most effective ways to remove lead from gasoline.

Because gasoline has inherent risk no matter how constituted, the conclusive proof of safety standard advocated by Mr. Walsh is impractical and unworkable. As one governmental health authority recently observed with respect to potential problems of alternatives to MMT®:

> *This situation highlights the difficulty and necessity of assessing the advantages and disadvantages of any alternative, and the caution with which the introduction of any alternative must be approached*. It should be noted that the amount of scientific information on the neurotoxicity of and exposure to manganese is substantial compared to the equivalent information on the toxicity and potential exposures associated with some of the alternatives.[12]

Without an analysis of the full range of alternatives and their associated risks, Mr. Walsh's paper fails to demonstrate -- as it must for application of the precautionary principle – the existence of cost-effective measures to replace MMT®.

Conclusion

As a MacArthur Foundation award winner and the recipient of other similar honors, Mr. Walsh is a knowledgeable and well-respected participant in the on-going dialogue concerning fuel and vehicle regulation around the globe. But even knowledgeable individuals can be misled from time to time. Mr. Walsh has proposed an unworkable interpretation of the precautionary principle that reflects an incomplete and skewed assessment of the science as it relates to MMT®. For this reason, Mr. Walsh's paper highlights precisely why great care is needed when applying the precautionary principle. Only with great care in its application can the attainment of the objectives of the precautionary principle – namely, the protection of public health and welfare - be assured.

Endnotes

[1] Walsh, Michael P., "The Global Experience with Lead in Gasoline and the Lessons We Should Apply to the Use of MMT®," American Jour. of Ind. Med. (Accepted May 11, 2007).

[2] EPA's master list is available on the internet at www.regulation.gov in docket "EPA-HQ-OAR-2005-0036" (Item "0055").

[3] 42 U.S.C. § 7545(c)(3).

[4] The Rio Declaration on Environment and Development was issued as part of the United Nations Conference on Environment and Development held in Rio de Janeiro from June 3 to 14, 1992. The precautionary principle can be found in Principle 15 of the Rio Declaration.

[5] Government of Canada, "A Framework for the Application of Precaution in Science-Based Decision Making About Risk" (2003), § 4.9, p. 12 (emphasis added).

[6] See www.aftonchemical.com.

[7] Office of the Auditor General of Canada, Environment Canada and Health Canada, Response to Petition No. 32 – Fuel Additive MMT (November 2001) (hereinafter "MMT® AG Petition"), Executive Summary (emphasis added) *available at* http://www.oag-bvg.gc.ca/domino/petitions.nsf/viewe1.0/704B3377E8CA0CB285256C5600689A6D.

[8] Id., ¶ 30.

[9] *See, e.g.*, Roos, J, Cunningham, L.J., Meffert, M., The Interaction of MMT® Combustion Products with the Exhaust Catalyst Face, SAE Paper No. 2007-01-1078; Meffert, M., Quinn, T., Guinther, G., Evaluation of Factors Affecting Vehicle Emission Compliance Using Regional Inspection and Maintenance Program Data, SAE Paper No. 2006-01-3406; Roos, J., Meffert, M., Cunningham, L., Hotchkiss, A., Openshaw, M., A Survey of American and Canadian Consumer Experience – The Performance of Late Model Year Vehicles Operating on Gasoline With and Without the Gasoline Fuel Additive MMT®, SAE Paper No. 2006-01-3405; Cunningham, L. J., et al., Assessing High-Cell Density Catalyst Durability with MMT® Fuel Additive in Severe Driving Conditions, SAE Paper No. 2005-01-3840; Cunningham, L.J., AAM/AIAM Fleet Test Program: Analysis and Comments, SAE Paper No. 2003-01-3287; Roos, J., et al., A peer-reviewed critical analysis of SAE Paper 2002-01-2894 "The impact of MMT® gasoline additive on exhaust emissions and fuel economy of low emission vehicles (LEV), SAE 2002-01-3287; Roos, J., et al., Reformulating gasoline for lower emissions using the fuel additive MMT®, SAE 2002-01-2893.

[10] Control of Hazardous Air Pollutants from Mobile Sources, Final Rule, EPA-HQ-OAR-2005-0036 (hereinafter "MSAT Rule"), p. 30.

[11] MSAT Rule, p. 127.

[12] MMT® AG Petition, *supra*, n. 6, ¶ 30.