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FROM: Timothy A. French

DATE: February 4, 2014

RE: **Review of IARC Monograph 105: "Diesel and Gasoline Engine Exhausts and Some Nitroarenes"**

On June 12, 2012, following a week-long meeting, the International Agency for Research and Cancer ("IARC") announced its decision that "diesel engine exhaust" should be classified as a "Group 1" carcinogen – "carcinogenic to humans." After a more than 18-month interlude, IARC has released the final version of Monograph 105: "Diesel and Gasoline Engine Exhausts and Some Nitroarenes" (hereinafter, "Monograph 105.")

This memorandum briefly summarizes the content of the 704-page Monograph 105, specifically as it relates to the different nature – quantitative and qualitative – of the exhaust from new-technology diesel engines ("NTDE"). Those highlighted differences establish that any increased risk classification for diesel engine exhaust does not automatically apply to NTDE.

What follows is a chapter-by-chapter review of Monograph 105, highlighting the text and discussion points that distinguish NTDE, and that establish that the Group 1 classification should not be deemed to apply to NTDE.

Preamble/General Remarks

In the "general remarks" section of Monograph 105, the IARC authors include (at p. 34) the following important reference to NTDE to help frame all of the ensuing chapters of the Monograph:

> To meet the most stringent current emission-control regulations, diesel engines must be designed and constructed according to modern technology, which includes wall-flow particulate filters and diesel oxidation catalysts, in combination with the use of diesel fuel that has a very low sulfur content; the most rigorous technology measures will be required only after 2014. The new diesel engine technology has been shown to reduce particulate mass emissions by more than two orders of magnitude. Although the implications for carcinogenicity are not yet know, *the "new technology" diesel engines, due to their much lower emissions of particulate matter, will probably bring about an improvement with regard to public health.* It should be noted that the human epidemiological studies reviewed in this Monograph were conducted before the introduction of the modern diesel engine technology. (Emphasis added.)

This frame of reference is a key element of Monograph 105, and should not be overlooked in future discussions of Monograph 105 and its implications. It is particularly important that the Monograph authors specifically noted that none of the diesel epidemiology studies that drove the reclassification of diesel engine exhaust involved any exposures to NTDE.

Chapter 1: Exposure Data

In Chapter 1 (at p. 42), the Monograph authors adopt the nomenclature that IARC panel representatives recommended for the different phases of development of diesel engine technology, as follows:

> In this Monograph, diesel engines that are unregulated for particulate emissions are referred to as "traditional technology diesel engines"; those that are fitted with wall-flow particulate filters and oxidation catalysts, and use ultra-low sulfur fuel are referred to as "new technology diesel engines"; and those that fall in between the two are referred to as "transitional diesel engines."

Chapter 1 includes a section (running from pages 46-54) on "new technology diesel engines" detailing the very substantial reductions in emissions across-the board from NTDE, and highlighting the results from Phase 1 of ACES. In addition, the chapter includes a section (running from pages 60-65) comparing the emissions from NTDE and current gasoline engines, and noting the similarities between the two. ("Gasoline PFI vehicles emitted PM in the same range as diesel engines fitted with a DPF.")

In discussing the exposure estimates for individuals working in occupations involving the utilization of diesel engines, Monograph 105 states (at p. 80) as follows:

> Because the exposure data were mainly collected between 1990 and 2005, these measurements predominantly reflect the use of traditional and transitional diesel engines.

Chapter 2: Cancer in Humans

In this chapter, the main tables (Tables 2.1 and 2.2, at pages 150-170, and 189-218) summarizing the results of all of the potentially relevant diesel epidemiology studies, include a specific reference to the "follow-up period" for each study, in other words, the potential periods (in years) of exposure to diesel engine exhaust. Those tables confirm that the most recent exposure period ended in 2003 (study of Danish urban bus drivers), and that most of the exposures at issue in the relevant epidemiology studies occurred in the 1960s-1980s, with a few studies extending into the 1990s. Thus, the Monograph Tables make it clear, as does the general remarks section, that none of the potentially relevant diesel epidemiology studies involved NTDE.

Chapter 3: Cancer in Experimental Animals

At the beginning of this chapter, the IARC authors specifically note that "[t]he whole diesel exhaust used in the studies evaluated here was generated from fuels and diesel engines produced before the year 2000." Accordingly, none of the toxicology studies discussed and relied on in Monograph 105 involved any exposure to NTDE.

Chapter 4: Mechanistic Data

This chapter includes some significant discussions of the concept of lung "overload" and its unique manifestation in the inhalation studies of rats. (See page 328, "The concept of 'overload' is central to the relevance of using studies of rodents to evaluate human health hazards from inhaled particles.") The chapter goes on to make the following statements (at pages 336, 421 and 463) regarding the "overload" mechanism:

> Rats have been shown to be uniquely susceptible to particle-induced lung cancer in comparison with mice and hamsters. Although some steps [in the conceptual framework of carcinogenesis] have been demonstrated in humans exposed to poorly soluble particles, it is not known to what extent humans are susceptible to particle-induced lung cancers.
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> The species specificity of the rat lung response to particle overload, and its occurrence with other particles types, has been described extensively. The rat model has limitations for studying the mechanisms of carcinogenicity involved in the induction of human lung cancer following the inhalation of whole diesel engine exhaust.
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> * * *
>
> The rat lung response to particle overload is species specific and its occurrence after exposure to other particle types has been described.

In reviewing the studies of animals exposed in vivo to diesel emissions, the ACES Phase 3A studies are cited (at pages 351 and 355) as studies showing no significant increases in mutagenic effects resulting from exposures to NTDE. Turing to in vitro studies, the Chapter 4 discussion notes (at page 394) that "the use of devices to reduce the rates of PM emissions can lead to substantial reductions in mutagenic activity when expressed per unit of engine work, per cubic meter of exhaust, or per kilometer travelled." The discussion goes on to note (at page 397) that "[s]everal studies reported that DPFs dramatically reduce the emission rate of mutagens associated with the soluble organic fraction of diesel engine exhaust particles," and that the "IARC Working Group acknowledged that exhaust aftertreatment devices can alter the genetic and related effects induced by diesel engine exhaust."

The Chapter 4 discussion of non-cancer endpoints similarly notes (at page 441) the different nature of NTDE and the limited relevance of earlier studies, as follows:

> Most of the findings discussed below are applicable to older types of diesel exhaust, which was emitted from diesel engines manufactured before 2007. However, a few of the studies reviewed here examined the toxicity of exhaust from modern diesel engines that has been referred to as "new-technology diesel

> engine exhaust." Because an understanding of the health consequences of new-technology diesel engine exhaust is important, a subsection regarding the limited studies that have been carried out has also been included below.

Interestingly, the specific subsection referenced in the above-quoted material is not actually contained in the ensuing text of Chapter 4. Nonetheless, the chapter does cite the work of McDonald (2012) (see page 413) for the proposition that lung inflammation and oxidative stress were not observed in mice exposed to emissions from a diesel engine equipped with a catalyzed ceramic trap and operating on low-sulfur fuel. "The composition of the exhaust was also significantly different, as expected based on the differences in technology."

Chapter 5: Summary

In the summary chapter, the IARC authors note (at page 451) that "[t]he exact qualitative and quantitative composition of exhaust depends on the fuel used, the type and age of the engine, the use of an emissions control system, the turning of the engine, and its pattern of use." The chapter also notes (at page 452) the advent of "new-technology" engine models that are characterized by the integration of wall-flow diesel particulate filters and diesel oxidation catalysts." The chapter then goes on to make the following statements (at page 457 and 461) pertaining to NTDE:

> The whole diesel engine exhaust in these [toxicology] studies were generated from fuels and diesel engines produced before the year 2000.
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> * * *
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> [E]vidence has also been found that exhaust aftertreatment can contribute to substantial reductions in the activity of extracts of diesel engine particulate matter or exhaust semi-volatile organic compounds of expressed per unit of engine work or volume of emitted exhaust. No comparative data were available to the Working Group to evaluate the genetic and related effects of new-technology diesel exhaust … [A]t the present time, new-technology diesel engines have not been evaluated thoroughly.

In light of all the foregoing, it is clear that the increased risk classification for diesel engine exhaust does not apply to (and was not intended to apply to) NTDE.

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