

Scientists Challenge EPA Methodology On Alleged Carcinogens

The first conference of the Diesel Automobile Association saw an impromptu debate between a representative of the Federal Environmental Protection Agency and scientists questioning the EPA methodology of merely searching out and prohibiting alleged carcinogens in the environment. This methodology has meant major changes and major increased costs in many industries over the last several years.

Held in New York City Nov. 28, the Association conference hosted representatives from major diesel engine manufacturers in the United States, France, West Germany, Japan, executives of petroleum companies, diesel research, component and fuel firms, and transportation researchers.

During the conference's first panel participants questioned the validity of a Nov. 12 statement released by the EPA titled "Precautionary Notice on Laboratory Handling of Exhaust Products." Treated sensationally in the east coast press, the release cited Agency findings that diesel fuel emissions were cancer-causing.

Dr. Delbert S. Barth, Deputy Assistant Administrator for Health and Ecological Effects of the Environmental Protection Agency, explained the EPA's standards and methods of testing. *Dr. Barth was answered by Dr. Richard Pollak, an embryologist with the New York-based consulting firm, Advanced Technologies, Inc. We excerpt below a portion of the Barth-Pollak interchange.*

Barth:... Since 1975, EPA has sponsored a study on diesel engine particulate emissions to determine mass emission rates and composition as a function of engine type and fuel composition....

The seven engine... were tested for mutagenicity in the Ames Salmonella-microsome mutagenicity assay. In very simplistic terms, the Ames assay consists of exposing, to a chemical or mixture of chemicals, a specially prepared strain of bacteria which will not grow unless amino acid histidine, is present. The Ames Procedure has been shown to be 85 to 90 percent accurate in detecting substances that are carcinogenic in whole animal studies. The assumption that mutagens identified by the Ames test are also potential carcinogens is basic to the screening test philosophy....

Employing the Ames assay procedure, we found that several fractions common to each engine showed significant mutagenic properties. The findings of mutagenic activity were not altogether unexpected since previously reported studies had identified chemicals in engine exhaust products which are known to be mutagenic carcinogenic.

Even with these limited data, we had to provide an assessment. We said that, given the data that EPA now had on diesel exhaust products, we recommend that as a prudent measure these products, when present in enclosed laboratory spaces, be treated as potentially hazardous materials, particularly when they are in a concentrated state.

...We said that at this time, we do not have sufficient data to make any reasonable estimate of the public health risk....

Since we have limited data we have embarked on a substantial health effects research program to try to determine the health effects, if any, that might result from human exposure to diesel engine exhaust products...

...We are conducting several types of studies. Because we obtained positive results in Ames bioassays, we have initiated two other bioassays to confirm the results we found in the Ames test. These bioassays involve mammal cell mutagenesis and oncogenic transformation. We will be conducting further *in vitro* bioassays on particulate sample collected from light duty diesel engines operated under different driving schedules and fuel combinations. If we can develop suitable *in vitro* procedures, we will attempt to conduct comparative studies on the possible mutagenic activity of particular emissions from the exhausts of various diesel and gasoline engines....

We are also trying to develop equipment to generate a surrogate diesel particulate atmosphere. If we are successful, we will perform depistion and clearance studies on selected animal species to determine where the diesel exhausts particulate deposits, its residence time, and the degree of clearance from the lung.

We recognize that this is an ambitious health effects research program, but in order to have a reasonable data base from which to determine the risk, if any, to the public such a data base is essential....

Pollak:... The Ames test is known as a general screening test for mutagenic materials: that is, materials which will cause mutations in bacteria which have been selected, especially selected, for their ease of undergoing mutation. Now there are two assumptions before I go any further, two assumptions which must be emphasized. One is that the Ames test can be extrapolated down to zero: that is, low doses will be as efficacious in bringing about mutagenesis as high doses. Secondly, it is assumed that you can extrapolate these results to human systems and other mammalian systems.

The first point about the Ames test — just to give people a familiarity (so that there is no mumbo-jumbo

about a system they are not too sure about.) You take a bacteria, and you select it for the following qualities. One is that if there is a lesion in its genetic system it cannot repair it; it doesn't have a good repair system, which any healthy organism does have. So, you select it so that it is permeable to any piece of material you want to test for. You grow this bacteria and you throw in your particle — a diesel exhaust particle that has been isolated and concentrated — and you know that that particle can get inserted into the cytoplasm of this bacteria and then do its dirty work....

Third, the bacteria has a special enzyme system which has the ability to take this particle...and break it down and transform it to other kinds of materials....The original particle might not be mutagenic, but once it's broken down into other particles, it might become mutagenic.

Then as Dr. Barth points out, you have this special bacteria, which is very susceptible to any kind of environmental insult. You grow it, you put in your material to be tested, and then you find out if it underwent a mutation.

...If it undergoes a mutation, then that, it is assumed, is the same process that induces cancer in an advanced organism — the mammalian cell or the human cell. Are the (results of the) Ames test correlatable to cancer causing entities in humans? In animal studies, which are not human studies, you find that, of 100 percent of substances that will not cause cancer in animals, 20 percent will cause mutations in bacteria, that is you get 20 percent false positives under the Ames test—so you're dealing with a fairly high degree of uncertainty as to your particular substance in question.

Then the reverse is that out of 100 substances that will cause cancer in animals, 85 percent will cause mutagens in others; some are much more carcinogenic than others; and the Ames test is better or worse, depending on which groups you use, and of course, on which bacteria you select for which chemicals...

Now, the second point is really much more to the heart of the matter. You have a substance that you know causes mutation, then you take it and animal-test it, and you do it in a very concentrated way. You do it in a concentrated form because of financial reasons, lifespan reasons, and so on — not because it in any way mimics what happens in nature, what happens in diesel exhaust or anything else....The real point is that high dose radiation effect, or high dose mutagenic agents have never, ever, been shown to extrapolate linearly to zero. And that's a very crucial thing, because the Ames test, and animal testing, assume the extrapolation to zero or your test procedures.

So

functioned for one thing only: it has functioned for a witchhunt by environmentalists against, basically, any industrial or technological product that they themselves do not like. For very overtly political purposes, various industries or sectors of the economy have been singled out and become the subject of this kind of terrorist cancer research program with the Ames program....

...Over 50 percent of basic biological research monies are now going for environmental screening programs. In other words, instead of trying to get at what really is the basis of cancer, of oncogenesis, and therefore getting a handle on it, controlling it, and understanding how to deal with it from a technological point of view and a societal point of view, the monies have been going into screening programs so that any and every chemical that's in the air can be selected for, tested for, and sure enough, found to be carcinogenic.

...If you are basically looking for a zero-growth economy, you actually want to set up conditions by which any technological progress can be stunted or stopped dead in its tracks by saying, "It causes cancer."

The diesel will actually come under an assault. Just as the National Environmental Policy Act of 1969 (NEPA) has been used against nuclear power development, diesel will come under a (similar) assault when these tests are released that will prevent any expansion plans; diesel plans will be loaded down with all kinds of "safety" devices....NEPA, as it was drawn up several years ago, was drawn up specifically *not* to protect the environment, but to give a handle to the environmentalists so that they could selectively go against various industries and realize the conditions of a zero-growth economy.

The scientific issues are bogus. The only way to go after scientific issues is to go after and develop basic science. The political issues are the ones that must be addressed. I gave you what the Ames test does to explain the bogus scientific methods being used to obscure the basic question that's at stake here... zero growth versus progress and technology.

By the end of the panel session, Dr. Barth offered to reiterate Dr. Pollak's criticism to his superiors at the Environmental Protection Agency, and recommend that the agency retract the statements released to the press linking diesel fuel to cancer.

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