ATTACHMENT E

Monsanto

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Raymond C. Loehr, Ph.D.
Chair, Executive Committee
Science Advisory Board
Office of the Administrator
United States Environmental Protection Agency
Washington, D.C. 20460

Re: Monsanto Company and Epidemiology Studies Concerning Dioxin

Dear Dr. Loehr:

Monsanto has learned of the EPA's receipt of highly inflammatory and inaccurate information pertaining to epidemiology studies involving Monsanto's Nitro, West Virginia plant. The materials forwarded to your office are contained within a legal brief submitted by the plaintiffs' attorney in the appeal of a lawsuit filed against Monsanto and includes allegations that published study data and results were falsified by the University of Cincinnati's Kettering Institute and by Monsanto in a purported effort to mislead the scientific world and public regarding the toxic effects of dioxin. These accusations were first issued years ago by the same lawyer in the same lawsuit and are utterly untrue and contrary to the record in that case.

Considering the genesis of these accusations it is recommended that they be examined critically, especially in light of the EPA's previous experience with this source during the Kemner trial at which several government witnesses (including Dr. Kloepfer of EPA and Dr. Kimbrough of CDC) testified. The Kemner trial at which these charges arose involved the claim that Sturgeon, Missouri was unsafe due to dioxin contamination and that its residents (plaintiffs in the suit) had been injured by the teaspoon of TCDD contained in the 19,000 gallons of orthochlorophenol crude spilled during a 1979 train derailment. These health claims were contrary to the conclusions reached by the EPA, the Center for Disease Control and the jury. Given the strident nature of the inaccurate and misleading representations contained in the materials in circulation within the Agency, Monsanto believes it is important that the record should be kept straight on the subject.

The central focus of the materials submitted to the SAB relate to the claim of "newly revealed fraud" in epidemiological studies relied on by the EPA, an allegation which in turn is premised upon a purported statistical "re-analysis" created by plaintiffs' counsel in the Kemner trial. Both the statistical "re-analysis" and the resultant assertions of fraud were wholly the product of the plaintiffs' lawyer, not any expert or trial witness. The attorney's "re-analysis" was not peer-reviewed and was simply constructed by the plaintiffs' lawyer in the trial as purportedly representing a valid substitute for the peer-reviewed studies which it attacked. The allegations within the legal brief which conclude that fraud was committed by Monsanto and that the actual published studies contained misleading data stem from the courtroom advocacy of plaintiffs' counsel, which was predicated on the use of manipulative and epidemiologically unsound statistical practices--not sound science.

The specific allegations forwarded to the SAB in the materials are easily rebutted by the record in the case. At trial, the plaintiffs' lawyer attempted to manipulate the statistical data underlying the two mortality studies performed on the Nitro plant population. The Zack/Suskind study was peer-reviewed and published in the Journal of Occupational Medicine in 1980. It was a mortality analysis of the Nitro plant population acutely exposed to the potentially high levels of dioxin present in the 1949 runaway reaction at the facility. The second study, referenced by plaintiffs' counsel was a Proportionate Mortality Ratio (PMR) study authored by Zack and Gaffey which was performed at the same plant but reviewed a cohort comprised of employees with long-term occupational exposure to low levels of dioxin from the production process. Accordingly, while there was potential overlap in the two cohorts, the studies focused on potentially different employees, levels of dioxin, and exposure periods. The studies were compiled independent of each other. At trial the plaintiffs sought to dispute the conclusions of the studies by resorting to the epidemiologically unsound practice of retrospectively rearranging the study cohorts to achieve a desired result.

During the trial the plaintiffs' lawyer combined the nine cancer deaths from the chronic exposure study performed by Zack and Gaffey with the other nine cancer deaths in the exposed cohort within the acute study compiled and published by Zack and Suskind. The selective construction of a new cohort of 18 cancer deaths was then compared by the lawyer with only the original 49 non-cancer deaths in the long-term exposure study by Zack/Gaffey. This statistical reshuffling was argued at trial by plaintiffs' lawyer as revealing for the first time an excess in cancer deaths which Monsanto had previously concealed, charges now transmitted to the EPA. Importantly, however, the merging of the cohorts by the plaintiffs' lawyer omitted the 23 non-cancer aths in the Zack/Suskind study which were essential to any

combined comparison of the two studies. This fatal statistical omission in the "re-analysis" by plaintiffs' counsel was not disclosed at trial until Monsanto was able to offer the clarification testimony of its Medical Director, Dr. George Roush, and called the Kettering Institute's Director, Dr. Raymond Suskind, to testify regarding his work. Counsel for plaintiffs never called Drs. Zack or Gaffey as witnesses regarding their study. If the plaintiffs' lawyer had included the 23 non-cancer deaths selectively omitted in his "re-analysis", a death rate of 18 cancer deaths out of 90 total deaths would have resulted and no excess cancer death rate would exist. (See the enclosed diagram depicting selective omission in plaintiffs' counsels "re-analysis" and the actual result.)

Contrary to the untrue accusations contained in the plaintiffs' appellate brief, it is clear that Dr. Roush did not suggest that any of the mortality studies at the Nitro plant were fraudulent or scientifically inaccurate. Enclosed with this correspondence is a copy of a pertinent portion of Dr. Roush's testimony establishing the points outlined above. Similarly, Dr. Suskind testified at the trial regarding the accuracy of the studies and that there was absolutely no effort to "conceal" evidence of health effects. A written offer of proof, signed by Dr. Suskind, is enclosed with this correspondence and directly rebuts the accusations contained in the plaintiffs' brief.

Examination of Dr. Suskind's written offer of proof by any scientist familiar with the literature regarding dioxin would make it apparent that there was a constant and broad effort by the plaintiffs' lawyer to mischaracterize results of peer-reviewed scientific studies published by a wide variety of authors, including Dr. Kimbrough. Of particular importance is the portion of the offer of proof commencing at page 22 which provides the background and the data pertinent to rebut the accusation that the case showed that Dr. Suskind was "alleged to have falsely stated that workers' nervous system and liver problems had disappeared by 1953". At trial, Dr. Suskind testified that the AMA's conclusions that certain dioxin-related health effects cleared with time was based upon his experience in examining certain Nitro plant employees in 1949 and then following their health over multi-year period. The offer of proof commencing at page 22 explains the accuracy of Dr. Suskind's publications on that point. The patently false accusation by plaintiffs' counsel that Dr. Suskind sought to conceal another physician's findings of psychoneurosis in exposed workers from the West Virginia Workmen's Compensation Commission is also covered in the written testimony of Dr. Suskind commencing at page 50. Repeatedly at the trial Dr. Suskind testified that the Commission knew and was told of specific facts regarding the finding of "psychoneurosis" by another physician but that the Commission rejected the suggestion that it was related to the 1949 autoclave incident. The court record

established that Dr. Suskind had appeared before the Workmen's Compensation Commission 30 years earlier and had personal knowledge of these facts.

In short, the accusations by the plaintiffs' brief, which have been transmitted within the EPA, are untrue, contrary to history and the record at trial. Any critical reviewer of the plaintiffs' legal brief should conclude that the allegations of fraud are not credible. Indeed, the allegation that the University of Cincinnati falsified health studies regarding the mortality of Nitro workers is belied by the fact that the conclusion it reached in its peer-reviewed morbidity study on that population--that no long-term health effects other then chloracne appeared to be present--was shared by another totally independent study conducted at the same time on the same employee population by Dr. Irving Selikoff of Mt. Sinai School of Medicine, who was employed by the union to conduct that study.

It is hoped that the EPA will correct any misapprehension within the Agency caused by the receipt of the plaintiffs' appellate brief. Please advise if you have any questions or require any further information. We are very disturbed by the false charges being made against Monsanto and Dr. Suskind and will, of course, fully cooperate with you in setting the record straight.

Sincerely,

James H. Senger

James H. Senger
Vice President
Environmental Policy Staff

JS/dlr

CC: Donald G. Barnes, PhD.
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