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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

IAG 37-02
Oct. '82

September 30, 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Ms. Mary Rose Hughes
Deputy Assistant Secretary
for Environment, Health
and Natural Resources
Department of State
Washington, D.C. 20520

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Dear Ms. Hughes:

This is to advise you that Don R. Clay's letter to Jack Blanchard, dated September 23, 1982, can be misconstrued as a correct reflection of the views of OPTS vis a vis the totality of MPD associated issues. It was not cleared by Dick Funkhouser or myself as it was exchanged between working members of an ad hoc group.

As we have stated before, MPD is not scientifically well designed to the purposes of new chemical screening under the Toxic Substances Control Act (TSCA). The Office of Pesticides and Toxic Substances's (OPTS) interests under the new chemical program focus mainly on chronic health effects and environmental effects. As such, MPD - which emphasizes physico-chemical information which is more readily and more accurately developed by existing Office of Toxic Substances (OTS) QSAR methodologies - is poorly suited to OTS' risk assessment needs. Of the MPD base set only the determinations of LD_{50}, the eye irritation test, and the Ames test are really health related. The LD_{50} and eye irritation tests relate to acute toxicity and do not help in the assessment of chronic toxicity (recall that PCBs are less acutely toxic than table salt). The Ames test can be useful for certain classes of compounds but its predictiveness across a variety of chemical classes is not sufficient to single it out as the sine qua non of mutagenicity screens. Besides, the Ames only picks up agents which are capable of directly reacting with DNA (themselves or as metabolites).

OPTS continues to question the utility of the limited but rigid testing scheme put forth in MPD. We believe that any testing required of industry to assure the public of the safety of new chemical entities in commerce should be specifically tailored to the compound, should not be restricted by MPD, and should be reasonably related to the economic ability of the compound to sustain the cost of testing.

We have great concern that MPD as presently stated would provide leverage for industry - especially foreign competitors of our domestic industries - to push to restrict EPA's ability to demand testing based on OPTS' best scientific judgement and instead substitute a rigid, "cookbook" approach to new chemical evaluation which we believe would not serve the public well. OPTS believes that TSCA as presently written incorporates the flexibility the Agency needs to do its job of protecting public health and the environment. OPTS continues to oppose any pressure - domestic or foreign - to introduce elements of rigidity into the new chemical screening program under TSCA.

Mr. Clay's references to the wording of the recommendation must be interpreted in light of OPTS' and EPA's general dissatisfaction with MPD as a concept. MPD is of no utility to us, therefore it matters little to EPA what EC does with MPD internally.

We do believe that any language addressing the MPD issue must convey the sense that MPD is only <u>one</u> of many possible approaches to new chemical evaluation. Our experiences indicate that it is probably among the least useful. It does, due to its limited scope and rigidity, pose a strong possibility of tying the agency's hands - to the benefit of industry and the disbenefit of the public. Therefore, if language cannot be found to suitably convey the above stated sense of MPD as only <u>one</u> way among many, we would not be supportive of closure on the MPD issue.

Sincerely yours,

John A. Todhunter, Ph.D.
Assistant Administrator
for Pesticides
and Toxic Substances

cc: Funkhouser