dismissed because the interests of justice do not require transfer. Should the court decide transfer is appropriate, however, defendant submits that this case should be transferred to the U.S. District Court for the District of Columbia."

The reply was filed for the agency by Roger J. Marzulla, Assistant Attorney General.

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CANCER CLASSES QUESTIONED IN FINAL REPORTS ON HALOGENATED ORGANICS

Final reports from the Halogenated Organics Subcommittee of the EPA Science Advisory Board's Environmental Health Committee again questioned EPA's carcinogen classification system and gave some encouragement to so-called "frontier" approaches. Earlier drafts of the reports had made similar statements (See Jan. 27, Page 16).

With some final wording "fillips," the reports stuck to earlier drafts, although they were sent to EPA Administrator Lee Thomas through the SAB Executive Committee. They covered methylene chloride (dichloromethane - DCM), perchloroethylene (perc), 1,2-dichloropropane, ortho-meta-para-dichlorobenzene, trichloroethylene and several dichloroethylenes.

The SAB critique of the DCM health assessment document concluded: "... The subcommittee concludes that the level of uncertainty is greater and that the hazard for DCM may be less than that expressed by the agency's classification system in its cancer risk assessment guidelines." Also, the subcommittee gave ncouragement to new approaches to cancer assessment in stating:

> "In considering an over-all weight of evidence approach to risk assessment, other factors such as the nature of the animal tumor response, mechanistic data (such as binding of the chemical to DNA), genotoxic activity and epidemiological data should also be discussed....
>
> "EPA should discuss the findings of several investigators (Shumann et al., Dow Chemical; Green et al., ICI, United Kingdom) that indicate that DCM or its metabolites do not exhibit any potential to alkylate liver or lung DNA following in vivo exposure. Such findings raise the clear possibility that dichloromethane may have produced its carcinogenic responses in mice by non-genotoxic mechanisms and may include an important contribution of cytotoxicity in the over-all tumorigenic response. Such data become particularly relevant as carcinogenicity was observed only at extremely high exposures and was absent at lower, potentially noncytotoxic doses...."

The final "perc" document raised similar issues, ranking perc as somewhere between the B2 (probable human carcinogen) rating of the EPA health assessment and C, limited animal evidence, but, as had the draft, the group saw no reason EPA shouldn't regulate C carcinogens, stating:

> "... From a scientific point of view, it seems inappropriate for EPA and other agencies to regulate substances that are classified B2 and not to consider regulation of compounds classified as C, regardless of the level of human exposure. In the case of B2, B1 or even A categorized compounds where exposure levels are

> low, EPA may, with scientific justification, decline to regulate because the potential health effects appear to be trivial in magnitude. A substance classified as C (limited evidence in animals) for which human exposure is high may represent a much greater potential threat to human health. ... In many instances, this appearance of safety results from not yet having the results from well-designed bioassays such as those conducted by the National Toxicology Program."

The EPA classification system offers, the group said, "necessarily arbitrary categories of risk." The subcommittee said EPA "should re-evaluate its labeling system and methods for characterizing uncertainty," adding, "It should also review whether to be more consistent with IARC's terminology."

A draft Drinking Water Criteria Document for 1,2-dichloropropane brought objections from the subcommittee for use of a 1986 NTP study. A drinking water equivalent level (DWEL) should not be derived from the study, the subcommitte said, noting a series of objections, including: "The histological evidence of toxicity in the testes and the structural relationship to the male reproductive toxin 1,2-dibromo-3-chloropropane are sufficient evidence that the chemical may be a male reproductive toxin...."

As with DCM and perc, the subcommittee's discussion of ortho-meta-para-dichlorobenzene objected to the carcinogenicity classification, stating: "The EPA staff has used a weight of evidence approach in recommending a classification of B2 for drinking water based upon the staff's review of existing animal studies. The reasoning offered for this conclusion is scientifically defensible, but it is not the only defensible conclusion. In assessing the issue of carcinogenicity, a key question is the weight that should be assigned to the rat data for purposes of extrapolating risk to humans. The assessment of this and other issues led most subcommittee members to conclude that this compound should more appropriately be classified as Category C of EPA's guidelines."

Trichloroethylene also was placed by the subcommittee "on the continuum between the categories B2 and C." Stating that trichloroethylene "has the potential to cause cancer in humans, but its potency is low," the subcommittee objected that an EPA addendum to an earlier health assessment document did not adequately present "the relatively moderate tumor responses and the uncertainties regarding most of the assumed endpoints."

The subcommittee's report on its review of a drinking water criteria document for 1,1-dichloroethylene and related compounds said the "major issue addressed was whether chronic toxicity data for 1,1-DCE should be used to calculate lifetime drinking water health advisory values for both cis- and trans-1,2-dichloroethylene." Noting EPA's proposal "to use this surrogate" the subcommitt e said this "appears plausible," but: "Nevertheless, great uncertainty will remain in generalizing from similarities in acute response to those found in chronic responses, and from the specific pattern of toxicity induced by one isomeric form to that potentially induced by the others ...."

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DE MINIMIS SHOULD BE USED TO ALLOW ETHYLENE OXIDE USE, EPA TOLD

De minimis should be used by EPA to allow the use of ethylene oxide (EO) in spices, the Ethylene Oxide Industry Council (EOIC) of the Chemical Manufacturers Association (CMA) told EPA in comments filed on the petition to revok the

food additive tolerance for use of the pesticide on spices (See April 27, Page 21, and May 11, Page 29). The council also asserted that the inhalation and gavage studies cited by Petitioner Stein "do not indicate that low-level ingestion exposure (to EO) would pose cancer risk."

The council requested that EPA deny the petition and stated, "EPA's current food additive regulation is a rational application of the well-established de minimis doctrine. The recent D.C. Circuit opinion in Public Citizen v. Young (the so-called 'Colors Case') does not foreclose a de minimis tolerance for EO. In fact, the court reaffirmed the general applicability of the de minimis doctrine to regulation of chronic hazards. The court took pains to state that, although Congress expressly repudiated de minimis under the color additive clause, this action would not necessarily apply to food additives or in other settings."

The CMA council noted that the de minimis principle has been used by a number of agencies under a number of statutes. It said, "The principle recognizes that agencies and the courts should not concern themselves with negligible risks."

The de minimis court decision, according to the council's comments, "implies that Congress intended a permissible weighing of risk versus benefits rather than a 'rigid' prohibition" in the case of food additives.

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DDVP USE DEFENDED BY GROCERY MANUFACTURERS AND PROCESSORS

Retention of the use of dichlorvos (DDVP) has been requested in comments filed with EPA by the Grocery Manufacturers of America, Inc. (GMA) and DFA of California, an Association of Dried Fruit and Tree Nut Processors (See May 4, Page 15).

"There is no evidence of a human cancer risk associated with DDVP," according to Dr. Crystal A. Willis, GMA Staff Scientist. Noting NTP's latest DDVP classification, she urged EPA "to critically review and weigh all biologically relevant information in their evaluation of DDVP" (See April 27, Page 53). Willis concluded:

> "GMA finds that there is only limited evidence of carcinogenicity of DDVP to animals and that there is no evidence of carcinogenicity to humans. Accordingly, GMA respectfully requests that EPA retain the registration of DDVP. We believe that a careful review of all the animal studies on DDVP in light of NTP's recent reevaluation will lead the agency to the same conclusion."

Her comments included four reasons why DDVP alternatives are not suitable: "1. Alternatives are substantially more expensive. 2. GMA members have indicated that alternatives to DDVP are less effective. 3. Because alternatives require more frequent application, foods and workers may actually be exposed to greater levels of pesticides. 4. Some alternatives are unacceptable because they result in off-flavors."

Frank A. Mosebar, DFA President, also commented on DDVP alternatives such as irradiation and controlled atmosphere, stating that they were not feasible. "The cost and logistical problems for either program are astronomical and are simply prohibitive to our industry," he declared.