

# Activities of the Environmental Protection Agency Concerning Phthalate Esters

by Steven D. Newburg-Rinn\*

EPA's activities concerning phthalate esters have been in four general areas, namely: (1) their status as toxic pollutants under the Clean Water Act; (2) their status as "new chemicals" under Section 5 of TSCA; (3) the potential risk to human beings posed by DEHP; and (4) finally, the need for testing phthalates with respect to their health and environmental effects.

## Clean Water Act

Pursuant to Section 304(a)(1) of the Clean Water Act, EPA is required periodically to review and publish criteria for ambient water quality. Under the authority of this section of the Act and in satisfaction of the Settlement Agreement in *Natural Resources Defense Council, et al., v. Train*, 8 E.R.C. 2120 (1976), modified, 12 E.R.C. 1833 (D.D.C. 1979), EPA is required to publish criteria documents for 65 pollutants which Congress, in the 1977 amendment to the Act, designated as toxic under Section 307(a)(1). Among the 65 designated compounds were the phthalate esters. In November, 1980, EPA's Office of Water Regulations and Standards made available an ambient water quality criteria document for several of the phthalate esters. These Section 304(a)(1) criteria are not rules and they have no regulatory impact. Rather, these criteria present scientific data and guidance on the environmental effects of pollutants which can be useful to derive regulatory requirements.

Under the Clean Water Act, these regulatory requirements may include the promulgation of water quality-based effluent limitations under Section 302, water quality standards under Section 303, or toxic pollutant effluent standards under Section

307. States are encouraged to incorporate criteria for toxic pollutants, based on this guidance, into their water quality standards. To date EPA has promulgated no standards for the phthalate esters.

The Water Quality Criteria Document for Phthalate Esters was prepared prior to the public release of NCI/NTP's di(2-ethylhexyl) phthalate (DEHP) bioassay results and therefore did not take into account the NCI/NTP finding that DEHP was a carcinogen in both rats and mice under the conditions of the test (1). The Office of Water Regulations and Standards is now in the process of updating the criteria document to reflect these recent results.

The Office of Water Regulations and Standards is also now considering a petition from Monsanto to remove butyl benzyl phthalate (BBP) from the priority pollutants list. No decision has yet been made on this petition.

## Premanufacture Review Notices Under Section 5 of the Toxic Substances Control Act (TSCA)

On December 13, 1979, the EPA was given notice under Section 5 of TSCA of an intent to manufacture (PMNs) six new chemicals, described as short-chain polymers of phthalic acid and various mixed alcohols and dihydric alcohols. What I am able to say about these PMNs is somewhat limited by

\*Test Rules Development Branch, Office of Toxic Substances, Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460.

confidentiality claims. Nevertheless, the basic issues are not confidential business information and I will briefly outline the facts. No health or environmental effects data were submitted by the manufacturer with its notice of intent to manufacture. However, the similarity of the PMN substances to alkyl phthalates allowed the Agency to use data on existing alkyl phthalates to guide its preliminary assessment of the PMN substances. Also during the review period for the PMN substances the Agency received preliminary reports concerning the results of the NCI/NTP DEHP bioassay (1). In view of the evidence of adverse health and environmental effects of certain existing alkyl phthalates and the structural similarities of the PMN substances to those compounds, the Administrator issued an order under Section 5(e) of TSCA prohibiting the manufacture of these substances pending the submission of data by the manufacturer to clarify and define their potential hazards. Instead of going forward with the process necessary to either challenge or comply with the Section 5(e) order, the manufacturer chose instead to withdraw its request to manufacture these six substances.

## DEHP Assessment Activities

Having received the preliminary indication from the NCI/NTP bioassay that DEHP was carcinogenic in rats and mice, the Agency also began a review of the potential cancer risk to humans that DEHP might pose. Questions concerning DEHP's carcinogenic potential are complex, as I am sure that the agenda of this conference makes clear. The Office of Toxic Substances has developed a preliminary risk assessment of DEHP which will be presented elsewhere in this program (2). I do want to note, however, that at this time questions concerning this preliminary evaluation of the potential risk to humans posed by exposure to DEHP are under review at the highest levels of EPA. Because no Agency-wide decision on DEHP's risk has yet been made, I want to emphasize the preliminary nature of this risk assessment of DEHP, and caution you against interpreting these views as EPA's position as an Agency on DEHP's risk to humans.

## Phthalate Testing Needs

The Interagency Testing Committee (ITC), established under Section 4(e) of TSCA, recommended in its First Report that the alkyl phthalates be tested with respect to their environmental effects (3). They noted the somewhat ubiquitous nature of environmental phthalate exposure. In its Seventh Report (submitted to the Agency after the prelimi-

nary DEHP bioassay results were available), the ITC added butyl benzyl phthalate and butyl glycolyl butyl phthalate to the priority testing list under TSCA, this time recommending both health and environmental effects testing (4).

Talks between industry and EPA concerning phthalate testing needs began in August of 1979 with a detailed submission from Monsanto on their environmental testing program for the alkyl phthalates (5). Monsanto already had an environmental testing program in progress and they were interested in and willing to undertake additional voluntary testing for environmental effects.

Although the Agency was in the process of evaluating health effects data on alkyl phthalates, health effects were generally not perceived at that time as a strong concern for that class of compounds by either the Agency or industry. As these discussions continued it became apparent that a joint effort by the phthalate manufacturers would be appropriate to broaden the scope of the testing proposals. Monsanto agreed to meet with other phthalate manufacturers through the Chemical Manufacturers Association (CMA) to explore the possibility of a joint testing program. Their efforts were quite successful and a meeting was set up between EPA and industry which included representatives from the CMA and five companies manufacturing phthalates. This meeting marked the beginning of CMA's key role in industry and EPA testing discussions, which initially were focused on environmental and exposure concerns.

In early 1980, the Agency became aware of the results of the NCI/NTP bioassay (1) on DEHP, showing it to be a carcinogen in rats and mice under the conditions of the test, and (2) on butyl benzyl phthalate, where the results were equivocal under the test conditions (6). The DEHP results heightened the concerns of the Office of Toxic Substances, as well as those of the phthalate manufacturers, over the possible human health risks of the alkyl phthalates. A program for testing for both health and environmental effects was therefore developed by the manufacturers and users and coordinated by the CMA (forming the Phthalate Esters Program Panel). A summary presentation of this program was made to the Agency in November of 1980, followed by more detailed discussions. From the start, the CMA program was reasonably comprehensive in the environmental area. However, the health effects testing proposed at that time was limited to a small group of compounds with a focus on elucidating the mechanism of action for DEHP regarding its oncogenicity. Further meetings, then, to expand the health effects testing and also to add some additional testing to the environmental effects program were held, beginning in December of 1980, and continuing up until the present.

As a final result of all of these meetings, the Agency and the CMA appear to be close to an agreement on an industry-sponsored program of testing which matches the major testing needs of the Agency. Industry's voluntary program will answer environmental effects questions relating to toxicity to aquatic organisms, environmental fate and transport and biodegradation of all fourteen identified high production alkyl phthalates and benzyl butyl phthalate. These compounds are produced in quantities near or greater than ten million pounds per year. As will be explained elsewhere in this program (7), the CMA proposal also includes a screening program to examine the health effects issues of oncogenicity and mutagenicity for a somewhat smaller group of nine alkyl phthalates and benzyl butyl phthalate (8). Selection of these compounds was based on both production and chemical structure considerations. Positive results for a given chemical will result in additional, long-term testing and screening of more chemicals in that particular chemical's subcategory. It is proposed by CMA that cooperation of the Agency and industry extend through the testing program. When CMA's detailed proposal is received by the Agency in the near future, we will be examining it very carefully to determine whether these voluntary efforts will make necessary a regulation requiring the health and environmental effects testing of the phthalate esters.

A few notes about the CMA health testing program are in order. It may appear on first impression that EPA's needs for testing differ from

CMA's. I do not think this is so. Both industry and EPA need to know more about phthalate toxicity, and government has no investment in phthalates being found to be either human health or environmental risks. While the CMA program is clearly experimental, it clearly could establish the toxicity of phthalates in addition to DEHP. I believe that our knowledge of phthalate toxicity will appreciably advance if CMA goes forward with this program. (Since this conference, the EPA has accepted, as of October 30, 1981, a CMA proposal to do health and environmental effects testing of the alkyl phthalates on a voluntary basis.)

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