

health, and moderate environmental toxicity. Under these circumstances, EPA believes that it is appropriate to consider exposure in its listing decisions (see position set out in November 30, 1994 **Federal Register** cited above). Therefore, EPA's review of BBP consisted of two main components: a toxicity evaluation and a release and exposure analysis. EPA has concluded that (1) human health effects from BBP are not expected to be significant for purposes of section 313, and (2) BBP's moderate environmental toxicity, coupled with a low concern for persistence and bioaccumulation, does not represent a significantly high level of risk for the purposes of section 313(d). Details of the review can be found in the proposed rule (52 FR 27226) and in the document entitled "Hazard Assessment of n-Butyl Benzyl Phthalate" in the public docket.

A. Toxicity Evaluation

1. *Human toxicity.* At the time of publication of the proposed rule, EPA had preliminarily placed BBP in EPA's weight-of-evidence cancer risk assessment Category D (i.e., available evidence inadequate to determine human carcinogenic potential). EPA later placed BBP in weight-of-evidence Category C (i.e., a possible human carcinogen based on limited evidence in animals).

BBP's classification is based upon a 1982 study conducted by the National Toxicology Program (NTP). Because of serious flaws in this study, NTP has undertaken a second animal study to evaluate the carcinogenicity of BBP. It was initially expected that results of this study would be available by 1994. EPA has waited for a number of years for the results of this study; however, there is currently no indication that the study will be completed and results made available in the near future. Therefore, EPA has decided to take action on this petition at this time using the existing cancer study. If the results of the NTP study indicate that BBP can reasonably be anticipated to cause cancer, EPA will re-evaluate the chemical and may consider re-adding BBP to the section 313 list of toxic chemicals.

This reclassification resulted from further review of the existing evidence; no new evidence has been found beyond that considered in EPA's initial review of this petition to delete BBP from the section 313 list. Therefore, EPA continues to believe that, while the limited animal evidence available for BBP suggests a possible carcinogenic effect, the study providing this evidence is flawed. Because of the flawed nature of the study, EPA has concluded that

BBP exhibits low toxicity for purposes of EPCRA 313(d)(2)(B) listing decisions. Accordingly, exposure consideration will be factored in. EPA has no evidence to indicate other potential human toxicity.

2. *Environmental toxicity.* As discussed in the proposal, EPA has concluded that BBP is moderately but not highly ecotoxic. There is low concern for potential bioconcentration, and the half-life for primary biodegradation of BBP is approximately 2 days, which indicates that the substance should have low persistence in the environment.

B. Release and Exposure Analysis

EPA has received and entered into the section 313 TRI data base more than 100 reports per year for BBP for reporting years 1987 to 1992. EPA examined these reports primarily for water releases, both directly to surface waters and through Publicly Owned Treatment Works (POTWs). For these years, from 18 to 53 companies reported water releases to POTWs and from 1 to 15 reported releases directly to surface water. For the releases to POTWs, EPA assumed (based on the physical and chemical characteristics of BBP) that BBP releases are 90 percent removed in wastewater treatment at the POTW before the final release to surface water.

EPA analyzed the 1987 reported release data to estimate the surface water concentrations based upon mean and low receiving stream flow data, where available. Where stream flow data were unavailable, the POTW mean effluent flow was used as a worst-case estimate. Where BBP releases were reported as a range (e.g., 1 to 499 lb/yr), the upper end of the release range was used as a conservative estimate for purposes of this section 313 analysis.

No firms were identified with a potential surface water concentration at or above the Lowest Effect Concentration (LEC) for BBP of 110 ppb (chronic aquatic ecotoxicity) under mean flow conditions. Under low flow conditions, two firms had a predicted concentration of this magnitude (200 ppb for one firm, and an unquantifiable, high concentration for the other site). The other 17 firms all had estimated surface water concentrations under low flow conditions of 30 ppb or less.

The release patterns from subsequent years were similar, and thus the analyses using 1987 data were considered representative of subsequent years. To confirm this assumption, an additional exposure review was conducted using 1992 release data (the most current data available). Estimates of concentrations downstream from TRI

facilities were made using recent stream flow data. Surface water concentrations for the five highest releasers of BBP ranged from 0.03 ppb to 1.0 ppb during mean flow conditions, and from 0.2 ppb to 18.8 ppb during low flow conditions. Only the 18.8 ppb value exceeds the Maximum Acceptable Toxicant Concentrations (MATCs) for several algal species. However, because the low flow conditions are only expected to occur during one 7-day event in 10 years, EPA does not believe that this will result in adverse effects to the environment. Efforts were made to check as many sites as feasible in addition to the five highest releasers, because moderate releases may lead to higher concentrations for streams with less dilution. The surface water concentrations for the stream found to have potentially higher concentrations were estimated to be less than 2 ppb during mean flow conditions, and less than 13 ppb for low flow conditions. Again, although the low flow concentrations may exceed the MATC for certain algal species, the duration of exceedence is not expected to be sufficient to result in significant adverse effects.

Human exposure potential to BBP was also examined. The aquatic concentrations at drinking water utilities under mean flow conditions are expected to be below 1 ppb (i.e., less than 1 microgram per liter). The two largest release facilities are both on the Delaware River, and their combined result (after accounting for treatment) is less than 0.7 ppb under mean flow conditions. These concentrations are not expected to result in significant adverse effects in humans.

IV. Conclusion of EPA's Review

The hazard review conducted in 1987 concluded that BBP has low toxicity with respect to human health and moderate environmental toxicity. There is no new data available which would cause EPA to change this assessment. EPA's review of the 1987 and 1992 TRI reports for BBP uncovered no potentially significant releases at mean flow conditions and only two potentially significant releases at low flow conditions. EPA's conclusion is that these releases do not raise sufficient concern about potential human or environmental exposures to warrant retention of BBP on the section 313 list.

After reviewing available data and the comment on the proposed rule, EPA continues to believe that BBP does not cause, nor can it reasonably be anticipated to cause, the adverse human health or environmental effects set forth in section 313(d). Accordingly, it is