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PRC Engineering
Suite 600
303 East Wacker Drive
Chicago, IL 60601
312-938-0300
TWX 910-2215112
Cable CONTOWENG

prc
Planning Research Corporation

12/1/86
Site: New Bedford
Break: 2.10
Other: 220384

3/10/89

NEW BEDFORD HARBOR ENDANGERMENT ASSESSMENT

TASK 2.2

DETERMINING DOSE-RESPONSE REFERENCE LEVELS (DRRLS)

DRAFT LETTER REPORT

Prepared for

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Waste Programs Enforcement
Washington, D.C. 20460

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PRC No.	:	15-5600-78
Prepared By	:	Alliance Technologies Corporation
Telephone No.	:	(617) 275-5444
EPA Primary Contact	:	Frank Ciavattieri
Telephone No.	:	(617) 223-1951

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PRC Engineering
Suite 600
303 East Wacker Drive
Chicago, IL 60601
312 938-0300
TWX 910-2215112
Cable CONTOWENG

prc
Planning Research Corporation

November 26, 1986

Mr. Frank Ciavettieri
U.S. EPA Region 1
JFK Federal Building
Boston, MA 02203

Dear Mr. Ciavattieri:

PRC Environmental Management, Inc. and its subcontractor, Alliance Technologies Corporation (formerly GCA Corporation, Technology Division) are pleased to submit two reports entitled, "New Bedford Harbor Endangerment Assessment, Task 2.1 - Determining the Dermal Absorption Rate of PCBs - Draft Letter Report" and "New Bedford Harbor Endangerment Assessment, Task 2.2 - Determining Dose-Response Reference Levels - (DRRLs) - Draft Letter Report."

Should you have any questions or wish to discuss these reports or the work assignment in general with me directly, please feel free to do so.

Thank you for your assistance and cooperation.

Sincerely,

PRC Environmental Management, Inc.

Eric S. Morton

Eric S. Morton
Public Health Scientist

ESM/klb

Enclosure

cc: Nancy Deck
Bruce Bakaysa (letter only)
Barb Myatt, Alliance Technologies Corp.

NEW BEDFORD HARBOR ENDANGERMENT ASSESSMENT
Determining Dose - Response Reference Levels (DRRLs)
Task 2.2 Letter Report

INTRODUCTION

Under Task 2.2 of the revised workplan dated 8 September, 1986, Alliance (formerly GCA) was tasked to identify or develop Dose-Response Reference Levels (DRRLs) for use in quantifying the risks associated with the major routes of exposure to PCBs. There were three subtasks identified under this task. Alliance has completed the first two of these subtasks, and has evaluated the feasibility of completing the third. This letter report summarizes Alliance's activities. It is organized as follows. The first two sections outline Alliance's activities and conclusions regarding Subtasks 1 and 2. The third section details the rationale for not completing Subtask 3, and gives an alternate methodology for quantifying risk. The last section summarizes additional activities performed by Alliance as requested by EPA Region I.

SUBTASK 1 DOCUMENT REVIEW

The first subtask Alliance performed was to obtain and review the document, Development of Advisory Levels for Polychlorinated Biphenyls (PCBs) Cleanup (May 1986), prepared by the U.S. EPA Exposure Assessment Group (EAG), with particular emphasis on Section 12 and Appendix D. Alliance also obtained more than 90 of the primary references cited in this document. Those references that pertain to chronic and subchronic toxicity (approximately 1/3 of the total) were reviewed and evaluated to determine whether the results of these studies are applicable to New Bedford Harbor exposures and an adequate basis for developing subchronic and lifetime DRRLs.

The studies that Alliance reviewed utilized a variety of laboratory animals (mice, rats, rabbits, mink, ferrets, nonhuman primates) to investigate many noncarcinogenic toxic endpoints, including but not limited to reproductive effects, liver effects and changes in the gastric mucosa. Although most of these studies did see these adverse effects occurring,

several basic problems were encountered that make the application of these studies to DRRL development difficult. Many of the studies did not use dose levels low enough to see a No Observable Effect Level (NOEL) or Lowest Observable Effect Level (LOEL). Those that did determine a NOEL or LOEL were in species that seem to be much less sensitive than primates. One study that was cited (Allen et.al. 1979) in an earlier draft version the Development of Advisory Levels for PCBs Cleanup (U.S. EPA, 1985) did find a NOEL for reproductive effects in nonhuman primates (rhesus monkeys) that was used at that time to develop a Lifetime Acceptable Intake (LAI). However, frank reproductive effects in mink have been seen after exposure to certain PCB isomers at lower levels than monkeys (Aulerich et.al., 1985). This could possibly be attributed to the fact that the mink were dosed in this study with pure hexachlorobiphenyl isomers while the monkeys were dosed with Aroclor mixtures. However, another mink study using Aroclors (Bleavins et.al., 1980) also showed mink to be a very sensitive species. In any case, EPA did not develop an LAI for noncarcinogenic effects in the Development of Advisory Levels for PCBs Cleanup (U.S. EPA, 1986) probably due to the lack of definitive NOELs and LOELs in applicably sensitive species, although this is never actually stated.

SUBTASK 2. SHORT-TERM DRRL

The EAG document (U.S. EPA, 1986) does, however, develop a short-term (10-day) health advisory level for PCBs of 0.01 mg/kg/day. This is based on an analysis of the most current data base in the document that shows that the experimental threshold for adverse effects of Aroclor 1254 (in a variety of laboratory animals) in studies of 30 days duration or less is at or near a dose of 1 mg/kg/day. The advisory level of 0.01 mg/kg/day includes an uncertainty factor of 10 to account for interspecies extrapolation and a factor of 10 to account for individual variability. This provides a combined uncertainty factor of 100, thereby protecting the most sensitive population. Alliance feels that this is a reasonable approach to use to evaluate short-term exposures to PCBs and that a level of 0.01 mg/kg/day can be used for calculating risks in the endangerment assessment.

SUBTASK 3. DEVELOPMENT OF SUBCHRONIC AND LIFETIME DRRLs

Under Subtask 3, Alliance was tasked to graph the data obtained from the document review performed in Subtask 1 in order to choose the most sensitive endpoint on which to base subchronic and lifetime DRRLs. After performing the document and primary literature review, Alliance believes that the current data are inadequate to perform this exercise, for the reasons outlined under Subtask 1 above. It would be very difficult to determine the shape of the dose-response curves with the data that are available. Therefore, although it would be useful to have subchronic and lifetime DRRLs in order to evaluate long-term noncarcinogenic effects, it does not seem feasible to develop them at this time. This conclusion is essentially what is concluded (if not explicitly stated) in the EAG document (U.S. EPA, 1986).

Alliance proposes, in the absence of available, applicable longer-term numbers, to use the 10-day short-term acceptable intake developed by EPA to evaluate noncarcinogenic effects for short-term exposures only. Long-term exposure can then be evaluated for carcinogenic effects, using the Carcinogen Assessment Group (CAG) PCB cancer potency of 4.34 $(mg/kg/day)^{-1}$. Although this is less than ideal, Alliance believes that it is the only solution feasible at this time. This approach was discussed with EPA Region I personnel at a meeting on 9/24/86, and EPA tentatively concurred with Alliance's conclusions.

ADDITIONAL ACTIVITIES

In addition to the activities listed above that Alliance performed as part of the work assignment, EPA Region I requested that Alliance review the methodology that was used by U.S. EPA, 1986 (Development of Advisory Levels for PCBs Cleanup) to derive permissible soil contamination levels. The purpose of this review was to determine whether the exposure parameters used in the EPA document were applicable to the potential exposures in the New Bedford Harbor area and whether therefore the numbers derived could be used for the New Bedford risk assessment. This section briefly outlines this analysis, and summarizes Alliance's recommendations on whether these numbers should be used to characterize risk in New Bedford Harbor (NBH).

In assessing soil PCB exposure, EPA looked at three exposure routes: ingestion, inhalation and dermal contact. For each of these routes, state-of-the-art calculations using generally accepted exposure parameters (such as contact rates and absorption fractions) were used to determine estimated daily intakes from each exposure route. The intakes by various exposure routes were then compared (using a hypothetical concentration of 1 μg PCB-1254/g soil for illustration), to determine which routes predominate under the site conditions hypothesized in the EPA document, and whether any are so insignificant that they should be eliminated from further analysis. If actual site conditions are different from those hypothesized, exposure routes may be more or less important than in the EPA example, as the EPA document points out at the end of Chapter 18.

EPA then calculated Aroclor-specific permissible soil contamination levels for four Aroclors: 1242, 1248, 1254 and 1260 for both uncovered surface contamination and soils with a 25cm thick clean soil cover. For each Aroclor under consideration, a separate exposure evaluation was made for the following classes of exposure location and route: 1) Exposure occurs on-site. This was further subdivided into: (a) sites which are readily accessible to children, and hence for which soil ingestion is a possibility , and (b) sites for which there is no possibility of soil ingestion, and hence exposure is only through inhalation; 2) sites which no population is assumed to enter within the radius of 0.1 km from the site; and 3) sites which no population is assumed to enter within the radius of 1 km from the site. For exposure condition 1 (a) above, soil ingestion and inhalation are considered, both for children with and without pica. For exposure conditions 1 (b), 2 and 3, only exposure through inhalation is considered. Dermal contact with soil is not factored into the calculations for any of the permissible soil levels; the reason for this is not stated in the EPA document. The implications of this for application to New Bedford Harbor is discussed later in this letter report. The PCB contamination levels were back-calculated (using the equations stated in the EPA document) to provide soil levels that would not exceed acute non-cancer (10-day, see Subtask 2) and chronic cancer effect levels at receptor points. The permissible levels are expressed as ranges because the low and high values for the soil-air partition coefficient are used in the evaluation of soil inhalation.

The analysis presented in the EPA document is a rigorous treatment of both exposure to and risk from PCBs. Many risk assessments would use PCB soil levels to determine hypothetical "exposure body dose levels" that are then compared to some "acceptable" body dose level (such as an acceptable daily intake, or ADI), or multiplied by a cancer potency factor to estimate incremental cancer risks. This risk assessment differs in that it determines permissible PCB soil contamination levels, or "clean-up levels", that actual PCB levels in soil onsite can be directly compared to. The tables of permissible PCB soil contamination levels in the EPA document can be used with confidence under certain specific conditions. However, as is stated in Chapter 20, Limitations of Application, "A particular situation may warrant a site-specific evaluation which may require the use of conditions different from what has been assumed in preparing the tables."

In the New Bedford Harbor Endangerment Assessment, exposure and risk from PCB contaminated sediments will be evaluated rather than soils. It is possible to extrapolate from soils to sediments; however, because of the difference in the nature of the two substances, certain changes in the exposure parameters should be made. For instance, dermal contact is more important in sediments than soils because sediments tend to adhere more readily to skin. Exposure via particulate PCB inhalation would be expected to be significantly less for sediments than dry soils. However, this exposure route should be considered since it has not been possible to conclude that the PCBs detected in both the GCA 1984 and NUS 1986 Ambient Air Monitoring Programs are inherently associated with only the vapor and not with the particulate phase (Kahn, 1986). In Chapter 18 of the Cleanup Advisory Levels Report (U.S. EPA, 1986), Comparison of Exposures by Soil Ingestion, Inhalation, and Dermal Contact, the example lifetime intake via dermal absorption is actually <u>more</u> than the lifetime intake via soil ingestion by a child without pica, even when soils rather than sediments are evaluated. It is not clear why the EPA document did not factor dermal absorption into the permissible soil levels, when intake levels via soil ingestion and dermal absorption are very close in the sample comparison. However, intake via dermal absorption becomes even <u>more</u> important under New Bedford Harbor site conditions than under the conditions hypothesized in the EPA document, for the reasons stated above. Therefore, Alliance believes that dermal contact with sediments should be evaluated quantitatively as part of the risk assessment.

Although there are limitations to the use of the numbers derived in the EPA document for risk assessment in the New Bedford Harbor area, there are several ways that these numbers or the methodology used to derive them could be used. The options are outlined below.

1) The permissible soil levels that were derived that are most applicable to New Bedford Harbor site conditions are described under exposure location and route 1 (a) above i.e. exposure to uncovered soil contamination occurs on site via both inhalation and soil ingestion by a child without pica. These numbers could be used for a comparsion to New Bedford sediment levels, with the caveat that these numbers consider only two of the three critical soil exposure routes and therefore probably underestimate the risk present.

2) The equations and methodology used to derive the permissible soil levels (i.e. Equations 8, 9, 10 and 24 in U.S. EPA, 1986) could be used to derive similar permissible soil levels, by modifying certain exposure parameters to better reflect New Bedford conditions, and by factoring dermal contact into the calculations. For dermal exposure, the amount of sediment contacted and the frequency of contact would probably increase. Parameters for nonpica sediment ingestion would probably remain the same. Inhalation is more difficult to assess, but it can probably be assumed that most of the exposure parameters would remain the same. However, there are still issues outstanding that must be resolved before any assessment of inhalation at New Bedford Harbor can be made, i.e. which data will be used and will the evaluation consider vapor state and/or particulate PCBs.

3) Another option which could be considered is to assess each route separately, using the same acceptable levels discussed in Subtask 2 (i.e. 10-day noncancer and lifetime cancer) and the applicable exposure parameters. In this way traditional "risk ratios" and "incremental cancer risks" would be calculated for each route of exposure, rather than actual "permissible soil contamination levels". All applicable routes of exposure (including dermal contact) would thereby be assessed separately. Then the calculated "exposure doses" for each route could be summed and analyzed to give a site-specific estimate of multi-route and multimedia risk.

Alliance believes that all of the above are viable options and would result in an adequate assessment of exposure to and risk from PCB contaminated soil. However, the final choice of which, if any, of the above options to utilize should take into account the needs of the Feasibility Study. This aspect should be explored further before the actual risk assessment is performed.

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