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RE: Interim Report on the Site-Specific Risk Assessment

This letter report describes the site-specific risk assessment for PCBs at Estabrook Elementary School, Lexington, MA prepared by Environmental Health & Engineering, Inc. (EH&E) for the Town of Lexington. Preliminary versions of the site-specific risk assessment have been reviewed by the Estabrook Advisory Committee (the Committee) as well as by representatives of Lexington Public Schools and Lexington Public Facilities (the Town). This interim report reflects assessment questions and exposure scenarios developed with input from the Committee and Town, including decisions made during the Committee meeting on October 6, 2010. The site-specific risk assessment will be updated if any additional information becomes available on background or school-related exposure conditions.

Objective

The objective of the site-specific risk assessment is to develop information intended to help understand and manage potential health risks of PCBs in the indoor air of Estabrook Elementary (the School). The risk assessment is used to identify targets for concentrations of polychlorinated biphenyls (PCBs) in indoor air of the School. The targets are intended to be protective of health and to reflect exposure concentrations and time-location patterns that are representative of Estabrook students, teachers, and staff. As with any health risk assessment, the results of the site-specific assessment do not define “unsafe” levels of exposure.

Background

Human health risk assessment is a process for estimating the likelihood of an adverse effect on an organism or population following exposure to a particular agent (IPCS 2004). Risk assessment takes into account the inherent characteristics of the agent of concern as well as the characteristics of the specific population of interest. In general terms, assessment of human health risk requires identification, compilation and integration of information on (i) health hazards of a chemical, (ii) human exposure to the chemical, (iii) and relationships among exposure, dose and adverse effects. Identification of uncertainties is an important component of human health risk assessments. The results of a risk assessment are useful for identifying options to manage risk and also for communicating with interested audiences.

Methodology

The approach to the site-specific risk assessment for Estabrook is grounded in methods developed by the U.S. Environmental Protection Agency (EPA) for evaluating concentrations of PCBs in indoor air of schools. The EPA method is based on assumptions about rates of PCB exposure and activity patterns that are intended to be representative of a typical school population in the United States. In the site-specific risk assessment for PCBs, EH&E relied upon information about exposure concentrations and time spent in various parts of the school that is more specific to the Estabrook community.

EPA Exposure Calculator

EPA developed an Exposure Calculator (an electronic spreadsheet) in which total exposure to PCBs from a variety of sources is compared to the reference dose (RfD) for a specific commercial mixture of PCBs known as Aroclor 1254. Both exposure and the RfD are expressed in units of nanograms of PCBs per kilogram body weight per day (ng kg^{-1} d^{-1}). Details of the EPA methodology and input parameters are available elsewhere (YYcite and/or footnote).

PCB exposure from background levels in the environment and indoor air of a school are both considered in the spreadsheet. Background exposure is derived from measured levels of PCBs in food, air, soil, and dust reported in scientific literature and assumptions about rates of food consumption, inhalation, and skin contact with soil and dust. The difference between the RfD for Aroclor 1254 and background exposure is used to determine PCB exposure at a school that would limit the total exposure rate to a level below the RfD. The concentration of PCBs in indoor air of a school equivalent to that exposure is then calculated from the amount of time in the school and inhalation rates expected for people in a school. The analysis is done for a typical individual in each of several age groups.

In the EPA spreadsheet, the calculated rate of exposure to PCBs is compared to the RfD for Aroclor 1254, a specific manufactured mixture of PCBs that was used for many purposes. EPA derived the RfD for this mixture of PCBs by applying an “uncertainty factor” of 300 to the lowest dose of PCBs found to produce an effect during a laboratory test with animals. In the laboratory test, rhesus monkeys were fed high concentrations of PCBs for more than five years. The lowest amount of PCBs fed to the monkeys was about 1000 times higher than levels to which humans routinely encounter PCBs in food and air. EPA took the lowest dose that led to any adverse effects in the monkeys, and then divided that by 300 to account for uncertainties about differences between monkeys and humans, duration of the test compared to duration of exposure in the real world, and differences in how sensitive individuals might respond.

Site-Specific Exposure Calculator

EH&E built upon the EPA Exposure Calculator to develop an assessment of background and school-related PCB exposure that is more specific to the School community than the generic assessment available from EPA.

The site-specific assessment relies upon background concentrations of PCBs that were measured at Estabrook, measured elsewhere in New England, or derived from more current studies than the information included in the EPA Exposure Calculator. Background concentrations of PCB in the environment that differ between the site-specific and EPA exposure calculators are shown in Table 1 [YY- this table exists already – P:\17228\Correspondence\Advisory Panel and School Committee\09-16-2010\Tables Figures\Table 7.11x17.docx]. Site-specific background values for PCBs in outdoor air, indoor air, soil, and dust are greater than the values relied upon by EPA. These differences make the site-specific assessment more conservative, i.e., unlikely to underestimate actual background exposure, than the EPA analysis. In contrast, background rates of exposure to PCBs in food are lower in the site-specific assessment than in the EPA assessment. The site-specific data are based on the Total Diet Study (TDS) done in 2003 by the U.S. Food and Drug Administration. The EPA data are also based on the TDS, but the 1997 version of the study. Use of the 2003 dietary exposure data makes the site-specific assessment more up to date than the EPA assessment.

The site-specific assessment also relies upon information about time spent inside and outside of school that is specific to the School. The site-specific time-location data were obtained from the Principal and teachers. Times that differ between the site-specific and EPA exposure calculators are also shown in Table 1 [YY-this part of the table needs to be updated by Taeko]. Children and staff were reported to spend less time in the School in comparison to the generic time-location information relied upon by EPA. These differences make the site-specific assessment more accurate for the School than the generic assessment prepared by EPA.

The site-specific assessment also relies upon the RfD developed by EPA for a second commercial product of PCBs, known as Aroclor 1016. This RfD was used in the site-specific assessment because of similarities between the composition of Aroclor 1016 and the mixture of PCBs observed in air samples collected at the School. The mixture of PCBs in air of the School is compared to the mixture in Aroclor 1016 and Aroclor 1254 in Figure 1. The RfD for Aroclor 1016 is 3.5 times higher than the RfD for Aroclor 1254. The direction of the difference indicates that the mixture of PCBs in Arocolor 1016 is less potent toxicologically than Aroclor 1254. Additional information on EPA's derivation of the RfD for Aroclor 1254 and Aroclor 1016 is provided in Table 2 [obtain from Figure 5 in the file P:\17228\Correspondence\Advisory Panel and School Committee\09-16-2010\Project Update 09.16.10.docx]. Use of the RfD for both Aroclor 1254 and Aroclor 1016 makes the site-specific assessment more realistic and comprehensive than the generic assessment prepared by EPA.

Assessment Scenarios

The site-specific exposure calculator was applied to four scenarios (A – D), each of which was developed to address a specific assessment question. In each scenario, the output of the analysis is an estimate of the average concentration of PCBs in indoor air of the School that yields an exposure rate equivalent to the RfD for Aroclor 1254 and Aroclor 1016.

<u>Scenario A: October 18, 2010 – October 17, 2011.</u> This scenario addresses a target for PCBs in indoor air of the School in consideration of exposures over one calendar year beginning the week of October 18, 2010. The start date for this scenario reflects an annual period during which students, teacher, and staff members are expected to occupy their regularly assigned rooms and engage in their regularly scheduled activities. In this scenario, the exposure calculator is applied to a child in the age range of 3 to less than 6 years old. Because children in this age group are assumed to have the highest rate of background exposure to PCBs, this analytical approach is health protective for older ages as well. Details of exposure concentrations and activity patterns for Scenario A are provided in Table 3 [Table needs to be made].

<u>Scenario B: August 31, 2010 – August 30, 2011YY.</u> This scenario addresses a target for PCBs in indoor air of the School in consideration of exposures over one calendar year beginning on the first day of school for students in the 2010 – 2011 academic calendar. The date range for

this scenario reflects a full year that includes the entire period during which measurements of indoor air PCB levels are available and the School was occupied according to a regular schedule. As a result, this scenario considers actual conditions in the School during the present academic year in the estimate of target concentrations for the remainder of the year. In this scenario, the exposure calculator is applied to a child in the age range of 3 to less than 6 years old. Because children in this age group are assumed to have the highest rate of background exposure to PCBs, this analytical approach is health protective for older ages as well. Details of exposure concentrations and activity patterns for Scenario B are provided in Table 4 [Table needs to be made].

Scenario C: Kindergarten – 12th Grade. This scenario addresses a target for PCBs in indoor air of the School in consideration of exposures over a hypothetical 13-year period in the Lexington Public School system. Long-term average exposure is considered for a student who is currently a 5th grader at the School and who was also a student at Estabrook from Kindergarten through 4th grade. The time scale and cohort for this scenario reflects a 6-year accumulation of School-related exposure. Because these children are assumed to have the longest duration of School-related background exposure to PCBs, the results for this group are also health protective for children who are currently in Grade 4 or lower. Details of exposure concentrations and activity patterns for Scenario C are provided in Table 5 [insert the exposure concentration and exposure factor information from P:\17228\Site-Specific Risk Assessment\Screen Level Calc.xlsx].

Scenario D: Time in School August 31, 2010 – August 30, 2011. This scenario addresses a target for PCBs in indoor air of the School that is specific to exposures occurring during school hours, a period during which the Town of Lexington has an ability to influence concentrations and activities. In this scenario, the exposure calculator is applied to a child in the age range of 3 to less than 6 years old. Because children in this age group are assumed to have the highest rate of background exposure to PCBs, this analytical approach is health protective for older ages as well. Details of exposure concentrations and activity patterns for Scenario D are provided in Table 6 [may not need this table, may be sufficient to say it is a subset of Scenario B].

Results

Aggregate background exposure for ages 3 – <6 years was 5.9 and 7.5 ng kg^{-1} d^{-1} for school and non-school days, respectively. PCBs in food and indoor air at home accounted for greater than 95% of aggregate background exposure.

The average concentrations of PCBs in indoor air of the School that yield time-weighted average daily exposures equivalent to the RfDs for Aroclor 1016 and 1254 are listed in Table 7. A chart of the results is provided in Figure 3. The concentrations range from 210 ng/m^3 based on the Aroclor 1254 RfD for Scenario A and B to 13,000 ng/m^3 for Scenario C and the Aroclor 1016 RfD. These target indoor air concentrations for the School reflect the background PCB exposure rates and in-school conditions described above for each scenario.

Table 7 Estimated Targets for Concentrations (ng/m^3) of Polychlorinated Biphenyls in Indoor Air of Estabrook Elementary School, 117 Grove Street, Lexington, Massachusetts for Four Scenarios

Scenario		Target Concentration in Indoor Air	
Identifier	**Description**	**Aroclor 1254 RfD[a]**	**Aroclor 1016 RfD[b]**
A	October 17, 2010 – October 16, 2011	210	980
B	August 31, 2010 – August 30, 2011	210	990
C	Kindergarten – 12th Grade	1,100	13,000
D	Time in School, August 31, 2010 – August 30, 2011	310	1,200

ng/m^3 nanograms per cubic meter
RfD reference dose for chronic exposure developed by U.S. Environmental Protection Agency

[a] RfD of 20 nanograms Aroclor 1254 per kilogram body weight per day.
[b] RfD of 70 nanograms Aroclor 1016 per kilogram body weight per day.

Discussion

This interim letter report describes the current version of a site-specific risk assessment conducted to identify targets for concentrations of PCBs in indoor air of Estabrook Elementary and to inform risk management and risk communication activities. Further refinements to the site-specific risk assessment will be made if additional information on potential exposures becomes available. Although only preliminary, this version of the risk assessment is intended to.

The site-specific risk assessment produced target indoor air concentrations of PCBs for children 3 – <6 years of age that are approximately 2-fold greater than results derived for the same age group in a generic assessment conducted by EPA. Differences between the site-specific and EPA assessment are attributable primarily to three factors. First, background exposure to PCBs in the site-specific assessment is approximately 50% lower than in the EPA assessment. The difference in background exposure is the result of using more the latest information on PCB levels in food available from the FDA Total Diet Study. Second, children at Estabrook spend approximately 15%YY less time inside the School compared to the assumptions made by EPA. Half-days every Thursday and selected other days is a large source of the difference in time at school between the site-specific and EPA risk assessments. Third, children at Estabook spend approximately 20% of their time each week in special classes (e.g., art, music, library) located outside of their regular classroom and airborne PCB concentrations in those locations have been shown to be approximately 30% less than in regular classrooms.

Strengths of the Site-Specific Risk Assessment

A principal strength of this assessment is the site-specific information on measured concentrations of PCBs in the School. Exposure concentrations for the school that were incorporated into the assessment include measurements of PCBs in indoor air, outdoor air, soil, and interior surfaces. In addition to being site-specific and current, these measurements are fully quality assured. Moreover, the provenance and representativeness of these data are also known fully; characteristics which are rarely known so well in many risk assessments.

Use of time-location patterns specific to students and staff of the School is another significant strength of this assessment. Information on time-location patterns was initially gathered through a survey instrument supplied to the School administration by EH&E. Subsequently, EH&E interviewed a group of teachers and the principal to validate responses to the questionnaire, obtain refined information on daily start and end times at the School, and ascertain details on special classes and services offered in the School. This information was used to explore the sensitivity of results to deviations from the baseline time-location patterns described in the Methodology section.

Reliance on background concentrations of PCBs in background air, soil, and dust for the New England region is also a strong attribute of the site-specific assessment. Region-specific data are presumed to be more representative of background concentrations in the School community than national data relied upon by EPA. The region-specific data incorporated into the background exposure component of this assessment are measurements of PCBs in indoor air, soil, and dust from a sample of homes in New Bedford, MA. These homes are described in Vorhees et al. (YY and YY) as ‘control’ conditions in New Bedford. Nevertheless, other parts of New Bedford are well known to have had significant PCB contamination as a result of past manufacturing and disposal practices. Uncertainties associated with use of these data are discussed in the next section.

Use of updated information on dietary exposure to PCBs is another positive attribute of this assessment. The updated information is based on the most recent (2003) FDA study of PCBs in food in which samples of over 250 foods were gathered from retail outlets in four regions of the United States. The 2003 FDA data yield lower background exposures than the dietary intake estimates made by EPA in its risk assessment for a typical school. EPA relied upon incomplete data from an earlier (1997) dietary intake study conducted by FDA. The difference between the 1997 and 2003 dietary exposure data is consistent with the commonly accepted scientific understanding that background concentrations of PCBs in the environment are decreasing over time.

Incorporation of the RfD for both Aroclor 1016 and Aroclor 1254 as health protective benchmarks also contributes to the rigor of the site-specific assessment. Consideration of both RfDs is an explicit recognition of the similarities between the mixture of PCBs in indoor air of the School and the two commercial mixtures. The use of both benchmarks provides a more complete range of results for consideration by risk managers and the School community.

Finally, the use of several exposure scenarios is another significant attribute of the site-specific risk assessment. Presentation of multiple scenarios was intended to address the range of interests expressed in Estabrook Advisory Committee meetings to date. Consideration of both prospective and retrospective exposures, as well as aggregate (i.e., total) and school-only exposures, is intended to inform risk management options more fully than reliance on only a single exposure scenario.

Uncertainty

In addition to having numerous notable strengths, the site-specific risk assessment is also subject to uncertainty about actual exposure to PCBs and the level of health risk that corresponds to that exposure. As cited in the World Health Organization guidance on *Uncertainty and Data Quality in Exposure Assessment*, consideration of these uncertainties is an important element of a human health risk assessment.

Constraints, uncertainties, and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

Incomplete information about actual levels of background exposure to PCBs is one area of uncertainty in the site-specific risk assessment. As noted previously in this report, concentrations of PCBs in background indoor air, soil, and interior dust of the School community were based upon measurements made in reference homes located in New Bedford, MA as reported by Vorhees et al. (YY). Because New Bedford has a history of significant PCB contamination, there is some concern that reference areas in New Bedford are not representative of background PCB exposures in the School community. In particular, reliance on the New Bedford data may lead to overestimates of background PCB exposure among occupants of the School. This possibility contributes to the conservative nature of the site-specific risk assessment. On the other hand, overestimation of background exposure could limit risk management options that are available to the Town, including strategies to control exposure concentrations, and could also complicate risk communication. In consideration of this uncertainty, an analysis was conducted to evaluate the sensitivity of the site-specific risk assessment to choices about the source of background exposure data. For this purpose, national average background data for indoor air, soil, and interior dust relied upon previously by EPA were substituted in place of the corresponding New Bedford data. The substitution led to a YY% increase in target indoor air concentrations of PCBs for the School.

Actual exposure to PCBs in food for the School community is another source of uncertainty in the site-specific risk assessment. As noted previously in this report, estimates of background dietary exposure were based upon results of a national survey of PCBs in food conducted by FDA in 2003. These dietary exposure data indicate that PCBs are present above FDA method detection limits in only two foods: salmon and catfish. The estimate of background dietary exposure for children 3 – <6 years assumes that a YY gram serving of salmon and YY gram serving of catfish is consumed every YY days on average, according to results of a YYyear food consumption survey conducted by USDA. Infrequent consumers of these fish may experience substantially less dietary ingestion of PCBs than the estimates derived from the 2003 data. The converse may be true for people who consume these food items more frequently.

Another interesting feature of the dietary data is that background exposure to PCBs through food for the 3 – <6 year age group decreased approximately 60% between the 1997 and 2003 FDA surveys of foods. As noted above, the downward trend suggested by these data is consistent with the commonly accepted scientific understanding that background concentrations of PCBs in the environment are decreasing over time. Therefore, current dietary exposure to PCBs in the School community may be lower than estimates derived from the 2003 data. The effect of any such difference on the results of this assessment would be to increase PCB levels in indoor air of the School that are commensurate with rates of PCB exposure equivalent to the RfD for either Aroclor 1254 or Aroclor 1016.

Variability of dietary exposure to PCBs among individuals raises other aspects of accounting for background exposure in the site-specific risk assessment. For instance, foods such as salmon are widely believed to confer positive nutritional benefits because of their levels of certain fatty acids. The trade-off between potential benefit and risk is not well characterized. In addition, food consumption patterns of people who occupy the School have not been quantified. Likewise, PCB levels in foods of markets in and around Lexington, MA have not been quantified. As a result, no site-specific information on background dietary exposure to PCBs is available at this time. Moreover, ingestion of foods that contain PCBs cannot be controlled, or perhaps even influenced, by the Town or School. The lack of complete information about background dietary exposure to PCBs, and variability of dietary intake among individuals, contributes to uncertainty in the site-specific risk assessment. The potential impact of that uncertainty on estimates of target concentrations for indoor air of the School was estimated by eliminating dietary exposure from the analysis. Target indoor air concentrations of PCBs increased by YY% for Scenarios YY when background dietary exposure to PCBs was omitted from the analysis.

Assumptions about prior exposure to PCBs in the School are a source of uncertainty about the results for Scenario C, which consider 5 years of retrospective exposure. Actual concentrations of PCBs in indoor air of the school during that time period are unknown. It is known however that concentrations are related to ventilation and ambient conditions. Many factors influence ventilation including time of day, exhaust fan operation, supply fan operation, thermostat setting, and use of operable windows. These factors are likely to have varied over time and among rooms in the School. With regard to ambient conditions, it should be noted that first round of air samples from the School was collected under summer conditions, which because of elevated temperatures may represent worst-case conditions for emissions of PCBs to air. In EH&E's experience, PCB levels in buildings often change with the seasons, with greatest emissions found in the heat of the summer months. During fall and winter, when outdoor temperatures fall and the building envelope cools, the amount of PCBs emitted to the air will decrease as well.

The range of results derived from the RfD for Aroclor 1016 and Aroclor 1254 also illustrates the scientific uncertainty present in the site-specific risk assessment. Targets for indoor air concentrations obtained from the two RfDs are intended to be protective of health and to reflect exposure concentrations and time-location patterns that are representative of Estabrook students, teachers, and staff. As shown in Figure 2, the distribution of PCB homologs in indoor air of the school is not identical to the homolog distribution for either Aroclor 1016 or Aroclor 1254. Instead, the observed homolog distribution appears to have elements of both commercial mixtures. While other commercial mixtures of PCBs, such as Aroclor 1221 or Aroclor 1242, may also be similar to the distribution of homologs observed in air of the School, EPA has yet to establish health protective guideline values (e.g., a RfD) for those mixtures of PCBs. Nonetheless, the target indoor air concentrations that correspond to the Aroclor 1016 and Aroclor 1254 RfDs represent a range of health protective results that can be considered by risk managers.

Uncertainty in the site-specific risk assessment is also related to the methods and information used by EPA to develop the RfDs for Aroclor 1016 and Aroclor 1254. As described in detail by EPA and summarized in Table 2, the RfDs were derived from laboratory studies of rhesus monkeys that were fed high concentrations of the respective commercial mixtures for at least five years. The lowest amount of PCBs fed to the monkeys was up to 1000 times higher than levels to which humans routinely encounter PCBs in food and air. EPA took the lowest dose that led to any adverse effects in the monkeys, and then divided that by 300 to account for uncertainties about differences between monkeys and humans, duration of the test compared to duration of exposure in the real world, and differences in how individuals might respond. When estimating target indoor air concentrations of PCBs in schools, both EPA and EH&E assumed that PCBs present the same hazards to health whether ingested or inhaled.

Extrapolation of toxicological results from laboratory studies of animals fed high amounts of commercial mixtures of PCBs to inhalation of much lower amounts of a different mixture of PCBs in schools presents substantial scientific uncertainty. EPA applied an uncertainty factor of 300 to the lowest dose of PCBs found to produce an effect during the laboratory tests with animals to account for the uncertainty in extrapolating that result to humans. Because the uncertainty factor was applied in only one direction and animals are known to sometimes be more sensitive than humans to effects of chemical exposure, the uncertainty factor is similar to a ‘safety factor’. Regardless of the terminology, the RfDs for Aroclor 1016 and Aroclor 1254 are not based on scientific studies of PCB exposure and effects in humans. In EH&E’s view therefore, the RfDs, and target indoor air concentrations derived from them, are most appropriately characterized as health protective, but not health-based.

Health-based guidelines for PCB exposure through inhalation would be derived from epidemiological studies. Based on extensive consulting EH&E has done with various governmental agencies, and extensive research of the scientific literature in this area, EH&E has not found any study that reports adverse health effects in children or adults who have occupied buildings with airborne levels of PCBs equivalent to those in the School.

The epidemiological and toxicological studies that do report associations between PCBs and human health indicate that PCBs only start to have negative effects after their levels have accumulated in human tissue. Motivated by that information, EH&E has carefully examined, and even conducted, research on levels of PCBs in people who have occupied buildings impacted by PCB-containing construction materials and inhaled PCB vapors for years at concentrations in the range of those measured at School. EH&E's extensive evaluation of these data has shown that exposure to PCBs in indoor air of buildings with air concentrations similar to the School do not result in increased amounts of total PCBs in the blood when compared to a reference population. Because epidemiological studies that report adverse effects of PCBs are predicated on elevated body burdens of PCBs, the lack of association between body burdens and occupancy of buildings with indoor air concentrations in the range of those measured in the School is an indication that PCB vapors at the School are unlikely to pose a substantive risk to health. The concentration of PCBs in humans is commonly understood to be largely related to age and gender, probably reflecting accumulation from food over time and differences in diet or other lifestyle attributes between men and women. That evidence provides further confidence that health risks at the School would only arise from long-term exposure to higher levels of PCBs than those found at the School.

Summary and Conclusion

EH&E completed a preliminary site-specific assessment of human health risk for PCBs at Estabrook School to help understand and manage potential risks. The objective of the assessment was to identify targets for concentrations of PCBs in indoor air of the School. These targets are available to support risk management and risk communication activities by the Town. Application of conventional methods for quantitative risk assessment to four exposure scenarios and two benchmarks for chronic exposure produced a range of target concentrations for PCBs in indoor air of the School. Principal uncertainties identified in the quantitative risk assessment include incomplete information on background exposure to PCBs for the School population and the type and likelihood of adverse effects in humans associated with inhalation of the mixture of PCBs present in indoor air of the School. Results of the quantitative risk assessment are further informed by studies of human populations known to have occupied buildings with PCB concentrations in indoor air similar to the levels observed in the School. These studies have not found associations between occupancy of the building and body burdens of PCBs. Because epidemiological studies that report adverse effects of PCBs are predicated on elevated body burdens of PCBs, the lack of association between body burdens and occupancy of buildings with indoor air concentrations in the range of those measured in the School is an indication that PCB vapors at the School are unlikely to pose a substantive risk to health.